

Version Française

Déclarant

Nom de l'entreprise

Nissha Medical Technologies SAS

Adresse

**23-25 Boulevard de la Paix
95800 Cergy
FRANCE**

Déclaration

En tant que fabricant légal, nous déclarons sous notre entière responsabilité que les produits de notre dossier Câbles Pressions sont conformes aux exigences applicables du règlement (UE) 2017/745 relatif aux dispositifs médicaux et à la Directive 2011/65/UE (RoHS) (révisée en 2015).

SRN number: FR-MF-000009791

Liste des produits marqués CE

Voir annexe ci-dessous.

Classe du risque

Classe I selon la règle 1 des critères de l'Annexe VIII « *RÈGLES DE CLASSIFICATION* » du règlement (UE) 2017/745 relatif aux dispositifs médicaux.

Classification GMDN et EMDN

GMDN: 47487 - Câble électrique pour appareil médical, usage général

EMDN: Z1203020301 - Surveillance de la pression artérielle invasive

EMDN: Z12030285 - Instruments de surveillance des signes vitaux – Consommables

Basic UDI-DI

037005063Pressure-CableV3

Evaluation de la conformité

Procédures Annexe II « *DOCUMENTATION TECHNIQUE* » et III « *DOCUMENTATION TECHNIQUE RELATIVE À LA SURVEILLANCE APRÈS COMMERCIALISATION* » du règlement (UE) 2017/745 relatif aux dispositifs médicaux.

Certificat SMQ

Organisme notifié

TUV Rheinland (0197)

Type de certificat

EN ISO 13485 : 2016

Champ

Conception et développement, fabrication et distribution de câbles, brins et accessoires pour la surveillance et la diagnostic des patients, câbles et accessoires pour l'électrochirurgie et la défibrillation, électrodes pré-câblées pour la surveillance et le diagnostic cardiaques, brassards et tuyaux de mesure de pression artérielle non invasifs. Fabrication et distribution de tubulures d'endoscopie non stériles. Distribution de moniteurs patient et accessoires, capteurs de signes vitaux et accessoires associés, électrodes (ECG / neutre / défibrillation), appareils d'électrochirurgie et accessoires associés, défibrillateurs et accessoires associés, équipements d'endoscopie et accessoires associés, papiers médicaux, bandages, bandes et EPI médicaux. Service pour les moniteurs patient.

No d'enregistrement

SX 1743273-1

Date de fin de validité

La date de validité de la présente attestation est de 2 ans à compter de la date de signature ci-après.

English version

Declarant

Company Name

Nissha Medical Technologies SAS

Address

**23-25 Boulevard de la Paix
95800 Cergy
FRANCE**

Statement

As legal manufacturer, we declare under our sole responsibility that the products from our dossier Pressure Cables meets the applicable requirements of the Medical Device Regulation (EU) 2017/745 and the Directive 2011/65/EU (RoHS) (amended in 2015).

SRN number: FR-MF-000009791

CE-mark Products list

See Annex below.

Risk classification

Class I according to rule 1 of the criteria of Annex VIII "CLASSIFICATION RULES" of the Medical Device Regulation (EU) 2017/745.

GMDN and EMDN classification

GMDN : 47487 - Medical Device Electrical Cable, General-Purpose

EMDN : Z1203020301 - Invasive blood pressure monitoring

EMDN: Z12030285 - Vital signs monitoring instruments – consumables

Basic UDI-DI

037005063Pressure-CableV3

Conformity Assessment

Procedures Annex II « TECHNICAL DOCUMENTATION » and III « TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE » of the Medical Device Regulation (EU) 2017/745.

QMS certificate

Notified Body

TUV Rheinland (0197)

Certificate Type

EN ISO 13485 : 2016

Scope

Design and development, manufacture and distribution of cables, leadwires and accessories for patient monitoring and diagnosis, cables and accessories for electrosurgery and defibrillation, prewired electrodes for cardiac monitoring and diagnosis, non-invasive blood pressure cuffs and hoses. Manufacture and distribution of non-sterile endoscopy tubing. Distribution of patient monitors and accessories, vital signs sensors and related accessories, electrodes (ECG / neutral / defibrillation), electrosurgery devices and related accessories, defibrillators and related accessories, endoscopy equipment and related accessories, medical chart papers, bandages, tapes and medical PPE. Servicing of patient monitors.

Registration No.

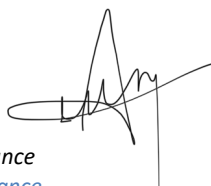
SX 1743273-1

End date of validity

This certificate is valid for 2 years from the date of signature below.

Cergy, 2022-03-29

Arnaud Cochetoux
Directeur general - France
General Manager – France



NISSHAMEDICAL.COM

Annexe

Annex

Référence Part Number	Description	UDI-DI	Référence Edwards Part Number Edwards
88115	CABLE COMPATIBLE EDWARDS SCHILLER ARGUS PB1000/2000/FYSICON	03700506308958	8960PBL1
88120	CABLE COMPATIBLE EDWARDS CRITIKON DYNAMAP	03700506308941	896019001
88162	CABLE COMPATIBLE EDWARDS DATASCOPE 2000/850/870/OMRON-COLIN	03700506308910	896004001
88225	CABLE COMPATIBLE EDWARDS ODAM/BRUCKER MAGLIFE-TM910-SM785	03700506308781	8960SMPNL
88320	CABLE COMPATIBLE EDWARDS HONEYWELL RM300	03700506308729	8960AXPNL
88330B	CABLE COMPATIBLE EDWARDS PHILIPS/AGILENT/HP	03700506307364	896083L1B
88330B-1.50M	CABLE COMPATIBLE EDWARDS PHILIPS/AGILENT/AHP	03700506308682	896083L1BS
88330B-10M	CABLE COMPATIBLE EDWARDS PHILIPS/AGILENT/HP	03700506308675	896083L1BS
88330B-2.50M	CABLE COMPATIBLE EDWARDS PHILIPS/AGILENT/HP	03700506308668	896083L1BS
88330B-2M	CABLE COMPATIBLE EDWARDS PHILIPS/AGILENT/HP	03700506308651	896083L1BS
88330-V2B	CABLE COMPATIBLE EDWARDS 2 VOIES PHILIPS/AGILENT/HP	03700506308620	896083L2B
88330-V2B-2M	CABLE COMPATIBLE EDWARDS 2 VOIES PHILIPS/AGILENT/HP	03700506308606	896083L2BS
88330-V3B	CABLE COMPATIBLE EDWARDS 3 VOIES PHILIPS/AGILENT/HP	03700506308590	896083L3B
88330-V3B-2.50M	CABLE COMPATIBLE EDWARDS 3 VOIES PHILIPS/AGILENT/HP	03700506308569	896083L3BS
88330-V3B-2M	CABLE COMPATIBLE EDWARDS 3 VOIES PHILIPS/AGILENT/HP	03700506308552	896083L3BS
88330-V4B	CABLE COMPATIBLE EDWARDS 4 VOIES PHILIPS/AGILENT/HP	03700506308545	896083L4B
88334	CABLE COMPATIBLE EDWARDS HP MERLIN	03700506308538	HP432
88343	CABLE COMPATIBLE EDWARDS CSI SCHOLLAR I-II-III 8100	03700506308477	896135001
88346	CABLE COMPATIBLE EDWARDS	03700506308446	8960MSPNL
88470	CABLE COMPATIBLE EDWARDS ARROW/KONTRON/LARSEN TOUBRO	03700506308415	896038001
88472	CABLE COMPATIBLE EDWARDS HUNTLEIGH 108/127/128A	03700506308408	896007011
88473	CABLE COMPATIBLE EDWARDS FUKUDA 7000	03700506308392	896508L1
88473-V2	CABLE COMPATIBLE EDWARDS 2 VOIES FUKUDA 7000	03700506308385	896508L2
88474	CABLE COMPATIBLE EDWARDS FUKUDA DENSHI 8000	03700506308361	8960DS001
88479	CABLE COMPATIBLE EDWARDS MAQUET/JOSTRA HL20	03700506308354	8960JTL1
88480	CABLE COMPATIBLE EDWARDS JOSTRA HL30	03700506308347	8960JLL1
88481	CABLE COMPATIBLE EDWARDS SARNS 3M/8000/9000/ATS1	03700506308330	8960GEPNL
88482	CABLE COMPATIBLE EDWARDS MAQUET/JOSTRA HLM	03700506308323	8960JSPNL
88483	CABLE COMPATIBLE EDWARDS SCHWARZER PICKER CARDIS 5000	03700506308309	8960SPPNL
88510	CABLE COMPATIBLE EDWARDS LEVITRONIX-CENTRIMAG	03700506308255	8960CML1
88510-2M	CABLE COMPATIBLE EDWARDS LEVITRONIX-CENTRIMAG	03700506308231	8960CML1BS
88530	CABLE COMPATIBLE EDWARDS NELLCOR/MDE ESCORT	03700506308224	896020001
88540	CABLE COMPATIBLE EDWARDS MENNEN 400/700 & HORIZON	03700506308200	896016011
88545	CABLE COMPATIBLE EDWARDS NIHON KODHEN LIFESCOPE/BSM	03700506308194	896031001
88550	CABLE COMPATIBLE EDWARDS MARQUETTE 7000/7010/TRAM I/II	03700506308170	896056001
88551	CABLE COMPATIBLE EDWARDS MARQUETTE EAGLE/DASH/SOLAR/TRAM/MAC	03700506308156	896507001
88551-3M	CABLE COMPATIBLE EDWARDS MARQUETTE EAGLE/DASH/SOLAR/TRAM/MAC	03700506308118	896507001S
88551-V2	CABLE COMPATIBLE EDWARDS 2 VOIES MARQUETTE EAGLE/DASH/SOLAR/TRAM/MAC	03700506308095	896507L2

88551-V3	CABLE COMPATIBLE EDWARDS 3 VOIES MARQUETTE EAGLE/DASH/SOLAR/TRAM/MAC	03700506308088	896507L3
88551-V4	CABLE COMPATIBLE EDWARDS 4 VOIES MARQUETTE EAGLE/DASH/SOLAR/TRAM/MAC	03700506308071	896507L4
88552	CABLE COMPATIBLE EDWARDS BARD Elektrophysion/Stamp	03700506308064	8960AZPNL
88554	CABLE COMPATIBLE EDWARDS GE/PRUCKA CARDIOLAB/EPLAB	03700506308057	896600PNL
88555	CABLE COMPATIBLE EDWARDS P/ MENNEN L=4M	03700506308040	800-060-592
88560	CABLE COMPATIBLE EDWARDS MINDRAY	03700506308033	8960MDL1
88570	CABLE COMPATIBLE EDWARDS MIRACOR MEDICAL SYSTEMS	03700506308026	8960MIRB1
88571	CABLE COMPATIBLE EDWARDS MIRACOR MEDICAL SYSTEMS	03700506308019	8960MIRR1
88630	CABLE COMPATIBLE EDWARDS MORTARA SURVEYOR	03700506307975	8960MRL1
88700	CABLE COMPATIBLE EDWARDS PHYSIO CONTROL LIFEPAK 12/VSM1-Ex	03700506307944	896025001
88710	CABLE COMPATIBLE EDWARDS PROPAQ. 104 VSM4/VSM5	03700506307937	896020001
88760	CABLE COMPATIBLE EDWARDS SIEMENS SIRECUST/GAMMA	03700506303564	896012013
88760-0.20M	CABLE COMPATIBLE EDWARDS DRÄGER/SIEMENS SIRECUST/GAMMA	03700506307838	8960SD900
88760-V2	CABLE COMPATIBLE EDWARDS 2 VOIES DRÄGER/SIEMENS SIRECUST/GAMMA	03700506307791	896012L2
88760-V3	CABLE COMPATIBLE EDWARDS 3 VOIES DRÄGER/SIEMENS SIRECUST/GAMMA	03700506307784	896012L3
88767	CABLE COMPATIBLE EDWARDS SIEMENS SC6000P/SC7000	03700506307760	8960SCPNL
88767-0.20M	CABLE COMPATIBLE EDWARDS SIEMENS SC6000P/SC7000	03700506307753	8960SCPNLS
88770	CABLE COMPATIBLE EDWARDS SIEMENS MINGOGRAPH	03700506307722	896079011
88780	CABLE COMPATIBLE EDWARDS S&W 8000/ARTEMA/GE CARDIOCAP/AS3/S5	03700506307715	8960CKPNL
88780-V2	CABLE COMPATIBLE EDWARDS 2 VOIES S&W 8000/ARTEMA/GE CARDIOCAP/AS3/S5	03700506307623	8960CKL2
88780-V3	CABLE COMPATIBLE EDWARDS 3 VOIES S&W 8000/ARTEMA/GE CARDIOCAP/AS3/S5	03700506307616	8960CKL3
88784	CABLE COMPATIBLE EDWARDS P/Witt Biomedical IV Physio	03700506307579	8960WBL1
88792	CABLE COMPATIBLE EDWARDS SPACELABS/PROPAQ/WELCH ALLYN	03700506307555	896021001
88792-5.5M	CABLE COMPATIBLE EDWARDS SPACELABS/PROPAQ/WELCH ALLYN	03700506307531	896021001S
88792-V2	CABLE COMPATIBLE EDWARDS 2 VOIES SPACELABS/PROPAQ/WELCH ALLYN	03700506307524	896021L2
88792-V3	CABLE COMPATIBLE EDWARDS 3 VOIES SPACELABS/PROPAQ/WELCH ALLYN	03700506307517	896021L3
88793	CABLE COMPATIBLE EDWARDS SPACELABS/IVY	03700506307487	896088011
88800	CABLE COMPATIBLE EDWARDS STOCKERT HLM/S3	03700506307425	896080001
88800-0.75M	CABLE COMPATIBLE EDWARDS STOCKERT HLM/S3	03700506307418	896080001S
88800-1.50M	CABLE COMPATIBLE EDWARDS STOCKERT HLM/S3	03700506307401	896080001S

Zgłaszający

Nazwa firmy

Nissha Medical Technologies SAS

Adres

**23-25 Boulevard de la Paix
95000 Cergy
FRANCE**

Oświadczenie

Jako legalny producent oświadczamy z pełną odpowiedzialnością, że produkty z naszej dokumentacji Przewody ciśnieniowe spełniają obowiązujące wymagania Rozporządzenia o Wyrobach Medycznych (UE) 2017/745 oraz Dyrektywy 2011/65/UE (RoHS) (zmienionej w 2015 r.).

Lista produktów CE

Patrz załącznik niżej

Klasyfikacja ryzyka

Klasa I zgodnie z zasadą 1 kryteriów załącznika VIII „ZASADY KLASYFIKACJI” rozporządzenia w sprawie wyrobów medycznych (UE) 2017/745.

Klasyfikacja GMDN and CND

GMDN : 47487 — Kabel elektryczny do urządzeń medycznych, ogólnego przeznaczenia

CND : Z1203020301 — Inwazyjne monitorowanie ciśnienia krwi

CND : Z12030285 — Przyrządy do monitorowania parametrów życiowych — materiały eksploatacyjne

Podstawowe UDI-DI

037005063 Kabel ciśnienia V3

Ocena zgodności

Procedury Załącznik II „DOKUMENTACJA TECHNICZNA” i III „DOKUMENTACJA TECHNICZNA NADZORU PO RYNKU”
Rozporządzenie w sprawie wyrobów medycznych (UE) 2017/745.

QMS certyfikat

Jednostka

notyfikowana

TUV Rheinland (0197)

Rodzajcertyfikatu

EN ISO 13485 : 2016

Zakres

Projektowanie i rozwój, produkcja i dystrybucja kabli, odprowadzeń i akcesoriów do monitorowania i diagnostyki pacjentów, kabli i akcesoriów do elektrochirurgii i defibrylacji, wstępnie okablowanych elektrod do monitorowania i diagnostyki serca, mankietów i przewodów do nieinwazyjnego pomiaru ciśnienia krwi. Produkcja i dystrybucja niesterylnych rurek endoskopowych. Dystrybucja monitorów pacjenta i akcesoriów, czujników parametrów życiowych i powiązanych akcesoriów, elektrod (EKG / neutralne / defibrylacja), urządzeń do elektrochirurgii i powiązanych akcesoriów, defibrylatorów i powiązanych akcesoriów, sprzętu do endoskopii i powiązanych akcesoriów, arkuszy medycznych, bandaży, taśm i środków ochrony osobistej . Serwisowanie monitorów pacjenta.

Numer

Rehestracji

SX 1743273-1

Data ważności

Data ważność niniejszego dokumentu wynosi 2 lata od daty podpisania znajdującej się poniżej.

Cergy, 2022-03-29

Arnaud Cocheteux
Directeur general - France
Dyrektor Generalny -
Francja



Załącznik

Référence Part Number	Description	UDI-DI	Référence Edwards Part Number Edwards
88115	CABLE COMPATIBLE EDWARDS SCHILLER ARGUS PB1000/2000/FYSICON	03700506308958	8960PBL1
88120	CABLE COMPATIBLE EDWARDS CRITIKON DYNAMAP	03700506308941	896019001
88162	CABLE COMPATIBLE EDWARDS DATASCOPE 2000/850/870/OMRON-COLIN	03700506308910	896004001
88225	CABLE COMPATIBLE EDWARDS ODAM/BRUCKER MAGLIFE-TM910-SM785	03700506308781	8960SMPNL
88320	CABLE COMPATIBLE EDWARDS HONEYWELL RM300	03700506308729	8960AXPNL
88330B	CABLE COMPATIBLE EDWARDS PHILIPS/AGILENT/HP	03700506307364	896083L1B
88330B-1.50M	CABLE COMPATIBLE EDWARDS PHILIPS/AGILENT/AHP	03700506308682	896083L1BS
88330B-10M	CABLE COMPATIBLE EDWARDS PHILIPS/AGILENT/HP	03700506308675	896083L1BS
88330B-2.50M	CABLE COMPATIBLE EDWARDS PHILIPS/AGILENT/HP	03700506308668	896083L1BS
88330B-2M	CABLE COMPATIBLE EDWARDS PHILIPS/AGILENT/HP	03700506308651	896083L1BS
88330-V2B	CABLE COMPATIBLE EDWARDS 2 VOIES PHILIPS/AGILENT/HP	03700506308620	896083L2B
88330-V2B-2M	CABLE COMPATIBLE EDWARDS 2 VOIES PHILIPS/AGILENT/HP	03700506308606	896083L2BS
88330-V3B	CABLE COMPATIBLE EDWARDS 3 VOIES PHILIPS/AGILENT/HP	03700506308590	896083L3B
88330-V3B-2.50M	CABLE COMPATIBLE EDWARDS 3 VOIES PHILIPS/AGILENT/HP	03700506308569	896083L3BS
88330-V3B-2M	CABLE COMPATIBLE EDWARDS 3 VOIES PHILIPS/AGILENT/HP	03700506308552	896083L3BS
88330-V4B	CABLE COMPATIBLE EDWARDS 4 VOIES PHILIPS/AGILENT/HP	03700506308545	896083L4B
88334	CABLE COMPATIBLE EDWARDS HP MERLIN	03700506308538	HP432
88343	CABLE COMPATIBLE EDWARDS CSI SCHOLLAR I-II-III 8100	03700506308477	896135001
88346	CABLE COMPATIBLE EDWARDS	03700506308446	8960MSPNL
88470	CABLE COMPATIBLE EDWARDS ARROW/KONTRON/LARSEN TOUBRO	03700506308415	896038001
88472	CABLE COMPATIBLE EDWARDS HUNTLEIGH 108/127/128A	03700506308408	896007011
88473	CABLE COMPATIBLE EDWARDS FUKUDA 7000	03700506308392	896508L1
88473-V2	CABLE COMPATIBLE EDWARDS 2 VOIES FUKUDA 7000	03700506308385	896508L2
88474	CABLE COMPATIBLE EDWARDS FUKUDA DENSHI 8000	03700506308361	8960DS001
88479	CABLE COMPATIBLE EDWARDS MAQUET/JOSTRA HL20	03700506308354	8960JTL1
88480	CABLE COMPATIBLE EDWARDS JOSTRA HL30	03700506308347	8960JLL1
88481	CABLE COMPATIBLE EDWARDS SARNIS 3M/8000/9000/ATS1	03700506308330	8960GEPNL
88482	CABLE COMPATIBLE EDWARDS MAQUET/JOSTRA HLM	03700506308323	8960JSPNL
88483	CABLE COMPATIBLE EDWARDS SCHWARZER PICKER CARDIS 5000	03700506308309	8960SPPNL
88510	CABLE COMPATIBLE EDWARDS LEVITRONIX-CENTRIMAG	03700506308255	8960CML1
88510-2M	CABLE COMPATIBLE EDWARDS LEVITRONIX-CENTRIMAG	03700506308231	8960CML1BS
88530	CABLE COMPATIBLE EDWARDS NELLCOR/MDE ESCORT	03700506308224	896020001
88540	CABLE COMPATIBLE EDWARDS MENNEN 400/700 & HORIZON	03700506308200	896016011
88545	CABLE COMPATIBLE EDWARDS NIHON KODHEN LIFESCOPE/BSM	03700506308194	896031001
88550	CABLE COMPATIBLE EDWARDS MARQUETTE 7000/7010/TRAM I/II	03700506308170	896056001
88551	CABLE COMPATIBLE EDWARDS MARQUETTE EAGLE/DASH/SOLAR/TRAM/MAC	03700506308156	896507001
88551-3M	CABLE COMPATIBLE EDWARDS MARQUETTE EAGLE/DASH/SOLAR/TRAM/MAC	03700506308118	896507001S
88551-V2	CABLE COMPATIBLE EDWARDS 2 VOIES MARQUETTE EAGLE/DASH/SOLAR/TRAM/MAC	03700506308095	896507L2

88551-V3	CABLE COMPATIBLE EDWARDS 3 VOIES MARQUETTE EAGLE/DASH/SOLAR/TRAM/MAC	03700506308088	896507L3
88551-V4	CABLE COMPATIBLE EDWARDS 4 VOIES MARQUETTE EAGLE/DASH/SOLAR/TRAM/MAC	03700506308071	896507L4
88552	CABLE COMPATIBLE EDWARDS BARD Elektrophysion/Stamp	03700506308064	8960AZPNL
88554	CABLE COMPATIBLE EDWARDS GE/PRUCKA CARDIOLAB/EPLAB	03700506308057	896600PNL
88555	CABLE COMPATIBLE EDWARDS P/ MENNEN L=4M	03700506308040	800-060-592
88560	CABLE COMPATIBLE EDWARDS MINDRAY	03700506308033	8960MDL1
88570	CABLE COMPATIBLE EDWARDS MIRACOR MEDICAL SYSTEMS	03700506308026	8960MIRB1
88571	CABLE COMPATIBLE EDWARDS MIRACOR MEDICAL SYSTEMS	03700506308019	8960MIRR1
88630	CABLE COMPATIBLE EDWARDS MORTARA SURVEYOR	03700506307975	8960MRL1
88700	CABLE COMPATIBLE EDWARDS PHYSIO CONTROL LIFEPAK 12/VSM1-Ex	03700506307944	896025001
88710	CABLE COMPATIBLE EDWARDS PROPAQ. 104 VSM4/VSM5	03700506307937	896020001
88760	CABLE COMPATIBLE EDWARDS SIEMENS SIRECUST/GAMMA	03700506303564	896012013
88760-0.20M	CABLE COMPATIBLE EDWARDS DRÄGER/SIEMENS SIRECUST/GAMMA	03700506307838	8960SD900
88760-V2	CABLE COMPATIBLE EDWARDS 2 VOIES DRÄGER/SIEMENS SIRECUST/GAMMA	03700506307791	896012L2
88760-V3	CABLE COMPATIBLE EDWARDS 3 VOIES DRÄGER/SIEMENS SIRECUST/GAMMA	03700506307784	896012L3
88767	CABLE COMPATIBLE EDWARDS SIEMENS SC6000P/SC7000	03700506307760	8960SCP NL
88767-0.20M	CABLE COMPATIBLE EDWARDS SIEMENS SC6000P/SC7000	03700506307753	8960SCP NLS
88770	CABLE COMPATIBLE EDWARDS SIEMENS MINGOGRAPH	03700506307722	896079011
88780	CABLE COMPATIBLE EDWARDS S&W 8000/ARTEMA/GE CARDIOCAP/AS3/S5	03700506307715	8960CKPNL
88780-V2	CABLE COMPATIBLE EDWARDS 2 VOIES S&W 8000/ARTEMA/GE CARDIOCAP/AS3/S5	03700506307623	8960CKL2
88780-V3	CABLE COMPATIBLE EDWARDS 3 VOIES S&W 8000/ARTEMA/GE CARDIOCAP/AS3/S5	03700506307616	8960CKL3
88784	CABLE COMPATIBLE EDWARDS P/Witt Biomedical IV Physio	03700506307579	8960WBL1
88792	CABLE COMPATIBLE EDWARDS SPACELABS/PROPAQ/WELCH ALLYN	03700506307555	896021001
88792-5.5M	CABLE COMPATIBLE EDWARDS SPACELABS/PROPAQ/WELCH ALLYN	03700506307531	896021001S
88792-V2	CABLE COMPATIBLE EDWARDS 2 VOIES SPACELABS/PROPAQ/WELCH ALLYN	03700506307524	896021L2
88792-V3	CABLE COMPATIBLE EDWARDS 3 VOIES SPACELABS/PROPAQ/WELCH ALLYN	03700506307517	896021L3
88793	CABLE COMPATIBLE EDWARDS SPACELABS/IVY	03700506307487	896088011
88800	CABLE COMPATIBLE EDWARDS STOCKERT HLM/S3	03700506307425	896080001
88800-0.75M	CABLE COMPATIBLE EDWARDS STOCKERT HLM/S3	03700506307418	896080001S
88800-1.50M	CABLE COMPATIBLE EDWARDS STOCKERT HLM/S3	03700506307401	896080001S



Edwards

EC Declaration of Conformity

Manufacturer: *Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614, USA*

European Representative: *Edwards Lifesciences Services GmbH
Edisonstraße 6
85716 Unterschleißheim, Germany*

Product category: *Single Use Devices and related accesories*

Product(-s): ***Hemodynamic Monitoring Disposables and related accesories***
Model codes, Names: see following pages

Classification: *See following pages
(According to Annex IX of the MDD)*

Conformity Assessment Route: *Annex II (excluding Annex II.4)*

UMDNS / GMDN Nomenclature: *See following pages*

Applicable Standard(-s): *See Essential Requirements Checklist of Technical File*

Start of CE Marking: *See following pages*

We herewith declare that the distributed CE marked products specified above conform to the product(s) covered by the “EC Certificate” issued and delivered by TÜV in accordance with Annex II (excluding Annex II.4) of the “EC Directive”, Council Directive 93/42/EEC, concerning Medical Devices. This declaration of conformity is issued under the sole responsibility of Edwards Lifesciences LLC. All supporting documentation is retained at the premises of the manufacturer.

In addition, we ensure and declare that the distributed CE marked products meet the provisions of the EC-Directives that apply to them.

The manufacturer has established and is maintaining a quality system which meets the requirements of EN ISO 13485:2016.

These directive(s) and standard(s) are supported by the following certificate(s):

Certificate Number	Valid until	Issued by	Holder of Certificate	Facility
G1 039555 0198	2024-05-26	TÜV SÜD Product Service	Edwards Lifesciences LLC, Irvine	Edwards Lifesciences LLC, Irvine*

*Denotes Design and Development facility

Notified Body: *TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München, Germany
Identification Number 0123*

Date: _____
Irvine, U.S.A

Aditi Iyengar Digitally signed by Aditi Iyengar
DN: cn=Aditi Iyengar, email=Aditi_Iyengar@edwards.com
Reason: I have reviewed this document
Date: 2022.04.07 16:29:40 -07'00'

*Aditi Iyengar
Senior Manager, Regulatory Affairs
Critical Care*

Introducer Product Components (Obturators)		
Class IIa / Rule 6		
UMDNS : 11925 Guide Wires		
GMDN : 35094 Catheter guide wire		
Model Code	Name	Date CE Marking first applied
GW3569I	Multi-Med® Central Venous Infusion Catheter Guidewires	26 June 2000
MO02F7P	Short AVA Obturator	11 Sep 2000
MO13F7P	Long AVA Obturator	30 Oct 2008

Introducer Product Components (Obturator Caps)		
Class IIa / Rule 7		
UMDNS : 16081 Caps		
GMDN : 42410 Cable/lead/sensor/probe cover, sterile		
Model Code	Name	Date CE Marking first applied
IOBCAP	Obturator Cap	29 May 2001

Introflex Introducer		
Class IIa / Rule 7		
UMDNS : 10678 Catheter Introducers		
GMDN : 58865, Vascular catheter introduction kit		
Model Code	Name	Date CE Marking first applied
I300F85	Intro-Flex® Percutaneous Sheath Introducers	26 June 2000
I300BF85	Intro-Flex® Percutaneous Sheath Introducers	26 June 2000
I301F6	Intro-Flex® Percutaneous Sheath Introducers	26 June 2000
I301F7	Intro-Flex® Percutaneous Sheath Introducers	26 June 2000
I301F8	Intro-Flex® Percutaneous Sheath Introducers	26 June 2000
I305BF9	Intro-Flex® Percutaneous Sheath Introducers	26 June 2000

Introflex Introducer		
Class IIa / Rule 7		
UMDNS : 10678 Catheter Introducers		
GMDN : 58865 Vascular catheter introduction set		
Model Code	Name	Date CE Marking first applied
I350BF85	Intro-Flex® Percutaneous Sheath Introducers	26 June 2000
I351BF7	Intro-Flex® Percutaneous Sheath Introducers	26 June 2000
I355BF9	Intro-Flex® Percutaneous Sheath Introducers	26 June 2000
I451BF6	Intro-Flex® Percutaneous Sheath Introducers	26 June 2000
I451BF8	Intro-Flex® Percutaneous Sheath Introducers	26 June 2000

CO-Set® Plus Closed Injectate System

Class IIa / Rule 2

UMDNS : 12134 Injectors, Thermal Dilution

GMDN : 10615, Thermal-dilution cardiac output unit

Model Code	Name	Date CE Marking first applied
93600	CO-Set® Plus Closed Injectate System	26 June 2000
93610	CO-Set® Plus Closed Injectate System	26 June 2000

CO-Set® Accessories

Class IIa / Rule 2

UMDNS : 13125 Probes, Thermometer

GMDN : 10615 Thermal-dilution cardiac output unit

Model Code	Name	Date CE Marking first applied
93505	CO-Set® Plus Flow-Thru Housing	26 June 2000

CO-Set® Accessories

Class IIa / Rule 2

UMDNS : 13929 Syringes

GMDN : 47017 General-purpose Syringe

Model Code	Name	Date CE Marking first applied
93650	CO-Set® Plus Syringe	26 June 2000

Multiple Lumen Access Devices

Class IIa / Rule 7

UMDNS : 16615 Catheterization Kits, Central Venous

GMDN : 58865, Vascular catheter introduction kit

Model Code	Name	Date CE Marking first applied
M3L85FSI	Multiple Lumen Access Devices	26 June 2000
M3L9FSI	Multiple Lumen Access Devices	26 June 2000

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
PX12N	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX1X2	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX200	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
PX212	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX24N	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX260	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX266C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX272	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX284	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX284AN	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX284R	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX2X2	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX2X2284C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX2X2YB	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX2X3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX36N	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX3X3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX3X3272	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX3X3284C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX3X3AN	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX3X3MT	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX4X4	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX600	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX600F	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX600FP	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	04 April 2007
PX600F30P	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	04 April 2007
PX600IP	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
PX600P	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	04 April 2007
PX600F30	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX600I	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX600INS	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX601	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX604	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PX604INS	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXAK1568	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXAK2066	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXAK2296	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXAVMP3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXCMK590	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK0010	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	19 June 2014
PXMK0011	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	19 June 2014
PXMK0012	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	19 June 2014
PXMK0013	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	19 June 2014
PXMK0014	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	19 June 2014
PXMK053	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK0666	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK0688	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK0692	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK0695	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK0774	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK0933	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
PXMK0940	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK0976	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1077	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1140	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1175	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1267	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1300	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1392	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1476	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1479	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1589	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1691	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1736	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1737	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1780	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1805	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1849	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1863	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1876	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK188	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1915	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1940	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1978	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK1997	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
PXMK2002	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2008	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2011	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2012	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2016	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2041	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2042	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2043	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2047	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2056	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2122	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2128	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2137	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2143	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2144	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2210	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2217	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2257	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2258	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2270	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2274	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2277	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2294	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2318	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
PXMK2319	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2320	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2326	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2329	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK2330	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK478	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK560	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK7729	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXMK9146	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 April 2013
PXVJ0441	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	22 April 2013
PXVJ0711	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	22 April 2013
PXVJ356	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	22 April 2013
PXVK0363	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVK0387	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVK0388	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVK0398	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVK0438	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVK0458	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVK0670	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVK0738	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVK0755	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVK0797	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVK0965	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVK1001	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
PXVK1003	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVK1006	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVK1086	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVK268	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVK282	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVMP120	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVMP160	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVMP172	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVMP184	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVMP260	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVMP272	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVMP284	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVMP2X21	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVMP2X31	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVMP3X31	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 April 2013
PXVP0549	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 April 2013
PXVP0686	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 April 2013
PXVP0812	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 April 2013
PXVP0861	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 April 2013
PXVP0880	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 April 2013
PXVP0897	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 April 2013
PXVP0902	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 April 2013
PXVP0966	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 April 2013
PXVP1066	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 April 2013

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
PXVP1087	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 April 2013
PXVP2260	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 April 2013
PXVP2272	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 April 2013
PXVP2284	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 April 2013
PXVP2284AT3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 April 2013
PXVP2284DZ	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 April 2013
PXVP23X3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 April 2013
PXVP23X3AT3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 April 2013
PXVP2X2AT3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 April 2013
T001619A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T001624A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T001631A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T001633A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T001645A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T001650A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T001657A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T001660A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T001670A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T001671A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T001691A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T001702A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T001709A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T001712A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T001713A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
T001724A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T001737A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T001741A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T001743A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T001744A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T001745A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T001746A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T001758A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T001759A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T001760A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T001765A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T001767A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T001775A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T001786A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T001789B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T001797B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T005002A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T005004A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T005005A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T005021A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	08 May 2000
T005021G	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	08 May 2000
T005025A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T005048B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T005049B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
T005050B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T005052A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T005074A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T005080A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T005086A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T005089A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	08 May 2000
T005091A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	08 May 2000
T005093A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T005094A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T100202A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T100209A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T100212A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T100214A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T100215A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T100500A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T100504A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T100671B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T270003B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T270004B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T270900A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T310195A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T310197A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T310682A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T310761C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
T310762A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T311058A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	08 May 2000
T312306A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T320137D	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T320139D	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T320161B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T320162C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T320544A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T320563A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T320564A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T320940B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T320941A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T320943A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T320947B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T321570A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T321571A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T321572A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T321573A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T321575A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T321811A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T321811Z	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	17 July 2014
T322238A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T322241A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T322242B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
T322244A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T322247A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T322251A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T322256A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T322515A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T323922D	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T323923A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T323924C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T323930D	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T323931C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T323932C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T325202A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T325306B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T325615A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T326207B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T328201A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T328500A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T330639B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T330831A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T330918A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T330919A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T330V11A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T331E02A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T331F06B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
T331S05B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T332J01A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T333529A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T333709B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T333710C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T333918A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T333919A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T333C00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T333D00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T333F00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T334041A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T334402A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T334708C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T336546B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T336547B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T336548B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T337003A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T337119B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T337305B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T341210A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T341211A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T341212A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T349301B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T349302A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
T391312A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T391313A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T391314A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T391608B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T391T00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T391T01A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T395606B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T395705A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T397704A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T397705B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T397708A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T398105B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T398603A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T398807D	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T398808A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T410001Z	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T410114B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T410115C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T413403C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T413405A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T413406A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T413642B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T413670A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T413675A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
T430023B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T430139A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T430140A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T430142A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T430168A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	08 May 2000
T430169A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	08 May 2000
T430177B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T430178B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T430179A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T430180A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T430181A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T430609A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T431108A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T431305A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T431514C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T432104B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T432105A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T432618G	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T432703A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T433201A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T433202B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T433204B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T433801A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T433802A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
T433803A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T433804Z	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T433806A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T434304A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T434500B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T434501B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T434502B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T440B20B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T440B21A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T440B26B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T440B27B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	24 October 2018
T440B28A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T441809C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T441L01A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T441T01C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T442J00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	24 October 2018
T443422A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T443952B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	08 May 2000
T447907A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T449103B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T450217A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T450544A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T450545A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T450553A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	08 May 2000

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
T451703A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T460061A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T460225D	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T460235A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T460237A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T460243A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T460249A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T460250A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T461803B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T470411B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	08 May 2000
T491U01B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T491Y01B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T492011A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T492F02B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T492F02Z	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	17 July 2014
T493Y02B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T493Y03B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T494C00B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T495009A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T530116B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T530217B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T530219A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T530219D	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T530223A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
T530310A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T530317A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T531401A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T531900A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T581201F	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T581203B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T610002A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T770000A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T770001A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T770002A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T770003A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
VMP306PX	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	22 April 2013
VMP406PX	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	22 April 2013
VMP426PX	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	22 April 2013
VMP448PX	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	22 April 2013
PXAK2253	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer)	22 April 2013
T001691M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP Plus Blood Management System, LASS)	23 July 2013
T005025M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer, LASS)	23 July 2013
T001741M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP Adult Blood Management System, LASS)	23 July 2013
T005021M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP FLEX Blood Management System, LASS)	23 July 2013
T470411M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP Jr. Blood Management System, LASS)	23 July 2013
T005050M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP Adult Blood Management System, LASS)	23 July 2013

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer*With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
T005091M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP FLEX Blood Management System, LASS)	23 July 2013
T100671M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP Plus Blood Management System, LASS)	23 July 2013
T005089M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP FLEX Blood Management System, LASS)	23 July 2013
T311058M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP FLEX Blood Management System, LASS)	23 July 2013
T430023M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP Plus Blood Management System, LASS)	23 July 2013
T001744M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP Adult Blood Management System, LASS)	23 July 2013
T490009M	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T490007A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
PXVPL0029	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer) & VAMP Plus)	01 Sep 2016
PXVPL0030	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer) & VAMP Plus)	01 Sep 2016
PXVPL0031	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer) & VAMP Plus)	01 Sep 2016
T100209B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	01 Sep 2016
PXMK0033	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	15 Dec 2016
PXVP0034	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer) & VAMP Plus)	15 Dec 2016
PXVP0035	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer) & VAMP Plus)	15 Dec 2016
PXVFL0059	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	15 Dec 2016
PXMK0074	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	11 October 2017
PXVJ0096	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Junior)	11 October 2017
PXVPL20001	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	24 January 2020
PXVKZ30006	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP)	24 January 2020
PXMK10012	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	24 January 2020

VAMP® (Blood Management System)

Class IIa / Rule 2

UMDNS : 10446 Sampling Kits, Blood

GMDN : 31336 Arterial blood sampling kit

Model Code	Name	Date CE Marking first applied
48AVMP	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	22 April 2013
48VMP106	VAMP Adult (Pressure Monitoring Set/Blood Management System)	25-May 2016
48VMP120	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	22 April 2013
48VMP160	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	22 April 2013
48VMP172	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	03 Dec 2004
48VMP184	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	22 April 2013
48VMP260	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	22 Jan 2007
48VMP272	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	03 Dec 2004
48VMP284	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	22 April 2013
VJ0990	VAMP Jr (Pressure Monitoring Set/ Blood Management System)	22 April 2013
VMP306	VAMP Jr (Pressure Monitoring Set/ Blood Management System)	22 April 2013
VMP406	VAMP Jr (Pressure Monitoring Set/ Blood Management System)	22 April 2013
VMP426	VAMP Jr (Pressure Monitoring Set/ Blood Management System)	22 April 2013
VMP448	VAMP Jr (Pressure Monitoring Set/ Blood Management System)	26 June 2000
VP0613	VAMP Plus (Pressure Monitoring Set/ Blood Management System)	22 April 2013
VP0753	VAMP Plus (Pressure Monitoring Set/ Blood Management System)	22 April 2013
VP1	VAMP Plus (Pressure Monitoring Set/ Blood Management System)	26 June 2000
VP181Z	VAMP Plus (Pressure Monitoring Set/ Blood Management System)	22 April 2013
VP2	VAMP Plus (Pressure Monitoring Set/ Blood Management System)	26 June 2000

VAMP® (Blood Management System) – with non-DEHP tubing/materials

Class IIa / Rule 2

UMDNS : 10446 Sampling Kits, Blood

GMDN : 31336 Arterial blood sampling kit

Model Code	Name	Date CE Marking first applied
VMP400	VAMP Needless Cannula (Pressure Monitoring Set/ Blood Management System)	26 June 2000
VMP600	VAMP Blood Transfer Unit (Pressure Monitoring Set/ Blood Management System)	22 April 2013
48VMP600	VAMP Blood Transfer Unit (Pressure Monitoring Set/ Blood Management System)	28 Feb 2018
VMP700	VAMP Direct Draw Unit (Pressure Monitoring Set/ Blood Management System)	22 April 2013
48VMP160	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	03 Aug 2016
48VMP260	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	03 Aug 2016
VMP306	VAMP Jr (Pressure Monitoring Set/ Blood Management System)	03 Aug 2016
VP1	VAMP Plus (Pressure Monitoring Set/ Blood Management System)	03 Aug 2016
VP2	VAMP Plus (Pressure Monitoring Set/ Blood Management System)	03 Aug 2016
VOPTIMA	VAMP Optima with Z-site + COMBICAP caps, 10-pack	28 Feb 2018
VOPTIMAL	VAMP Optima with LASS + COMBICAP caps, 10-pack	28 Feb 2018
VPL2	VAMP Plus (Blood Management System)	04 June 2019
48VMPL284	VAMP Adult (Blood Management System)	25 July 2019

FloTrac sensor

Class IIa / Rule 10

UMDNS : 16909 Transducers, Pressure, Disposable

GMDN : 35927 Transducer, pressure, single use

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
MHD6AZ	FloTrac sensor with adult VAMP Kit, 60" tubing	29 Aug 2005
MHD6	FloTrac sensor, 60" tubing	29 Aug 2005
MHD8	FloTrac sensor, 84" tubing	29 Aug 2005
MHD6AZR	FloTrac sensor with adult VAMP Kit, 60" tubing, red stopcock inserts	18 April 2008
MHD6R	FloTrac sensor, 60" tubing, red stopcock inserts	18 April 2008
MHD8R	FloTrac sensor, 84" tubing, red stopcock inserts	18 April 2008
MHD6AZ5	FloTrac sensor, 60" with VAMP, 5 pack	23 Dec 2008
MHD65	FloTrac sensor, 60", 5 pack	23 Dec 2008
MHD85	FloTrac sensor, 84", 5 pack	23 Dec 2008
MHD6S	FloTrac sensor, 60", extra stopcock, 5 pack	23 Dec 2008
MHD8S	FloTrac sensor, 84", extra stopcock, 5 pack	23 Dec 2008
MHD6AZA	FloTrac sensor, 60", anesthesia VAMP, 5 pack	23 Dec 2008

FloTrac sensor

Class IIa / Rule 10

UMDNS : 16909 Transducers, Pressure, Disposable

GMDN : 35927 Transducer, pressure, single use

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
MHD6AZR5	FloTrac sensor, 60", VAMP, red caps, 5 pack	23 Dec 2008
MHD6R5	FloTrac sensor, 60", red caps, 5 pack	23 Dec 2008
MHD8R5	FloTrac sensor, 84", red caps, 5 pack	23 Dec 2008
MHD8C503	FloTrac sensor, 84", w/ TruWave DPT	11 Sep 2017

FloTrac/FloTrac IQ/Acumen IQ/VolumeView sensor – with non-DEHP tubing

Class IIa / Rule 10

UMDNS : 16909 Transducers, Pressure, Disposable

GMDN : 35927 Transducer, pressure, single use

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
VLV8R5	VolumeView Sensor	03 Aug 2016
MHD6R	60in FloTrac Standalone	03 Aug 2016
MHD6AZR	60in FloTrac with Adult Vamp	03 Aug 2016
MHD6AZR5	60in FloTrac with Adult Vamp	03 Aug 2016
MHD8R	84in FloTrac Standalone	03 Aug 2016
MHD6R5	60in FloTrac Standalone	03 Aug 2016
MHD8R5	84in FloTrac Standalone	03 Aug 2016
MHDQ8R5	FloTrac IQ Sensor, 84", Red Caps, 5 Pack	09 Jan 2017
FTAFM8R5	FloTrac IQ Sensor, For AFM 84" / 213cm, 5 Pack With Red Caps	16 Mar 2017
HSFTQ8R5	FloTrac IQ Sensor for HemoSphere 84"/213CM 5-Pack with Red Caps	22 Nov 2017
MHD8VZ	FloTrac sensor + IV Set + VAMP Optima with Z-Site + COMBICAP caps, single pack	22 Dec 2017
MHDQ8VZ	FloTrac IQ sensor + IV Set + VAMP Optima with Z-site + COMBICAP caps, single pack	22 Dec 2017
MHD8VZ5	FloTrac sensor + IV Set + VAMP Optima with Z-site + COMBICAP caps, 5-pack	22 Dec 2017
MHDQ8VZ5	FloTrac IQ sensor + IV Set + VAMP Optima with Z-site + COMBICAP caps, 5-pack	22 Dec 2017
MHD8VRL	FloTrac sensor + IV Set + VAMP Optima with LASS + COMBICAP caps + red striped tubing, single pack	22 Dec 2017
MHDQ8VRL	FloTrac IQ sensor + IV Set + VAMP Optima with LASS + COMBICAP caps + red striped tubing, single pack	22 Dec 2017
MHD8VRL5	FloTrac sensor + IV Set + VAMP Optima with LASS + COMBICAP caps + red striped tubing, 5-pack	22 Dec 2017
MHDQ8VRL5	FloTrac IQ sensor + IV Set + VAMP Optima with LASS + COMBICAP caps + red striped tubing, 5-pack	22 Dec 2017

FloTrac/FloTrac IQ/Acumen IQ/VolumeView sensor – with non-DEHP tubing

Class IIa / Rule 10

UMDNS : 16909 Transducers, Pressure, Disposable

GMDN : 35927 Transducer, pressure, single use

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
MHD8VZTW	FloTrac sensor + IV Set + TruWave DPT + VAMP Optima with Z-site + COMBICAP caps + blue striped tubing, 5-pack	22 Dec 2017
MHDQ8VZTW	FloTrac IQ sensor + IV Set + TruWave DPT + VAMP Optima with Z-site + COMBICAP caps + blue striped tubing, 5-pack	22 Dec 2017
MHDQ8VLTW	FloTrac IQ sensor + IV Set + TruWave DPT + VAMP Optima with LASS + COMBICAP caps + red striped tubing + blue striped tubing, 5-pack	22 Dec 2017
MHD8VLTW	FloTrac sensor + IV Set + TruWave DPT + VAMP Optima with LASS + COMBICAP caps + red striped tubing + blue striped tubing, 5-pack	22 Dec 2017
MHD8VRZ5	FloTrac sensor + IV Set + VAMP Optima with Z-site + COMBICAP caps + red striped tubing, 5-pack	25 Oct 2018
MHD8VRZTW	FloTrac sensor + IV Set + TruWave DPT + VAMP Optima with Z-site, + COMBICAP caps + red striped tubing + blue striped tubing, 5-pack	25 Oct 2018
AIQS6R	Acumen IQ Sensor, 60", Red Caps	13 Dec 2018
AIQS6R5	Acumen IQ Sensor, 60", Red Caps, 5-pack	13 Dec 2018
AIQS8R	Acumen IQ Sensor, 84", Red Caps	13 Dec 2018
AIQS8R5	Acumen IQ Sensor, 84", Red Caps, 5-pack	13 Dec 2018
AIQS6AZR	Acumen IQ Sensor with VAMP System 60" with Red Cap	21 May 2019
AIQS6AZR5	Acumen IQ Sensor W/ VAMP Adult 60" with Red Cap, 5-pack	21 May 2019
AIQSAFM8R5	Acumen IQ Sensor for use with Assisted Fluid Management software feature, 5-pack	21 May 2019
AIQS6S	Acumen IQ, 60" / 152CM (Shield)	04 June 2019
AIQS8C503	Acumen IQ, 84" / 213CM Double Line Kit - No VAMP	04 June 2019
AIQS8S	Acumen IQ, 84" / 213CM (Shield)	04 June 2019
AIQS8S102	Acumen IQ, 84" / 213CM Double Line Kit -- With VAMP	04 June 2019

FloTrac IQ/Acumen IQ sensor

Class IIa / Rule 10 UMDNS : 16909 Transducers, Pressure, Disposable

GMDN : 35927 Transducer, pressure, single use

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
MHDQ6AZ	FloTrac IQ Sensor with Adult VAMP Kit, 60" tubing	30 Sep 2016
MHDQ6	FloTrac IQ Sensor, 60" Tubing	30 Sep 2016
MHDQ8	FloTrac IQ Sensor, 84" Tubing	30 Sep 2016

FloTrac IQ/Acumen IQ sensor

Class IIa / Rule 10UMDNS : 16909 Transducers, Pressure, Disposable
 GMDN : 35927 Transducer, pressure, single use

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
MHDQ6AZR	FloTrac IQ Sensor with Adult VAMP Kit, 60" Tubing, Red Stopcock Inserts	30 Sep 2016
MHDQ6AZ5	FloTrac IQ Sensor, 60" with VAMP, 5 pack	30 Sep 2016
MHDQ85	FloTrac IQ Sensor, 84", 5 pack	30 Sep 2016
MHDQ8R5	FloTrac IQ Sensor, 84", red caps, 5 pack	30 Sep 2016
MHDQ65	FloTrac IQ Sensor 60"/152CM	16 Mar 2017
MHDQ6AZA	FloTrac IQ Sensor with VAMP 60"/152CM	16 Mar 2017
MHDQ6AZR5	FloTrac IQ Sensor with VAMP ADULT 60"/152CM 5-Pack with Red Cap	16 Mar 2017
MHDQ6C502	FloTrac IQ Sensor 60"/152CM Double Line Kit – with VAMP	16 Mar 2017
MHDQ6R	FloTrac IQ Sensor 60"/152CM with Red Cap	16 Mar 2017
MHDQ6R5	FloTrac IQ Sensor 60"/152CM 5-Pack with Red Cap	16 Mar 2017
MHDQ6S	FloTrac IQ Sensor 60"/152CM (Shield)	16 Mar 2017
MHDQ8C503	FloTrac IQ Sensor 84" / 213CM Double Line Kit – No VAMP	16 Mar 2017
MHDQ8R	FloTrac IQ Sensor 84" / 213CM with Red Cap	16 Mar 2017
MHDQ8S	FloTrac IQ Sensor 84" / 213CM (Shield)	16 Mar 2017
MHDQ8S102	FloTrac IQ Sensor 84" / 213CM Double Line Kit – With VAMP	16 Mar 2017
FTAFM8R5	FloTrac IQ Sensor for AFM 84" / 213CM 5-Pack with Red Cap	16 Mar 2017
HSFTQ8R5	FloTrac IQ Sensor for HemoSphere 84"/213CM 5-Pack with Red Caps	22 Nov 2017
AIQS6	Acumen IQ Sensor, 60"	13 Dec 2018
AIQS65	Acumen IQ Sensor, 60", 5-pack	13 Dec 2018
AIQS6R	Acumen IQ Sensor, 60", Red Caps	13 Dec 2018
AIQS6R5	Acumen IQ Sensor, 60", Red Caps, 5-pack	13 Dec 2018
AIQS8	Acumen IQ Sensor, 84"	13 Dec 2018
AIQS85	Acumen IQ Sensor, 84", 5-pack	13 Dec 2018
AIQS8R	Acumen IQ Sensor, 84", Red Caps	13 Dec 2018
AIQS8R5	Acumen IQ Sensor, 84", Red Caps, 5-pack	13 Dec 2018
AIQS6AZ	Acumen IQ with VAMP System 60" / 152CM	21 May 2019
AIQS6AZ5	Acumen IQ W/ VAMP Adult 60"/152cm 5-Pack	21 May 2019
AIQS6AZA	Acumen IQ with VAMP System 60" / 152CM	21 May 2019

FloTrac IQ/Acumen IQ sensor

Class IIa / Rule 10UMDNS : 16909 Transducers, Pressure, Disposable
 GMDN : 35927 Transducer, pressure, single use

With VAMP:

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
AIQS6AZR	Acumen IQ with VAMP System 60" / 152CM with Red Cap	21 May 2019
AIQS6AZR5	Acumen IQ W/ VAMP Adult 60"/152cm 5-Pack with Red Cap	21 May 2019
AIQS6C502	Acumen IQ, 60" / 152CM Double Line Kit with VAMP	21 May 2019
AIQS6S	Acumen IQ, 60" / 152CM (Shield)	21 May 2019
AIQS8C503	Acumen IQ, 84" / 213CM Double Line Kit - No VAMP	21 May 2019
AIQSAFM8R5	Acumen IQ, for use with Assisted Fluid Management software feature	21 May 2019
AIQS8S	Acumen IQ, 84" / 213CM (Shield)	21 May 2019
AIQS8S102	Acumen IQ, 84" / 213CM Double Line Kit -- With VAMP	21 May 2019

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer with Non-DEHP Tubing

With TruWave Disposable Pressure Transducer:

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

Model Code	Name	Date CE Marking first applied
T001670A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	25 Jan 2013
T001671A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	25 Jan 2013
T001624A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	07 June 2013
T001775A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	07 June 2013
T100671B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	07 June 2013
T460061A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	07 June 2013
T460235A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	07 June 2013
T461803B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	07 June 2013

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer with Non-DEHP Tubing

With TruWave Disposable Pressure Transducer:

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

T470411B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	07 June 2013
T005074A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	07 June 2013
T310844A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	30 September 2015
T310845A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	30 September 2015
T310846A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	30 September 2015
T310847A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	30 September 2015
T451702A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T451703A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 May 2000
T001673A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T434303A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 May 2000
T001725A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T450552C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	08 May 2000
T001658A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T433803A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 May 2000
T320941C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	15 October 2015
T320943B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	15 October 2015
T331U03C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	15 October 2015
PXVJ050M	LASS Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr) with Non-DEHP Tubing	15 October 2015
T310761C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
PX2X2YB	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T333919A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T333C00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T333F00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T330831A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer with Non-DEHP Tubing

With TruWave Disposable Pressure Transducer:

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

PX284AN	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T331F06B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T333D00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T334708C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T332J01A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T331E02A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T334041A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T334402A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T337119B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T330918A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T331S05B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T333918A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T321571A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T333709B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T323932C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T531401A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T330V11A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T337305B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T333710C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T336546B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	03 Aug 2016
T336547B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	03 Aug 2016
T336548B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	03 Aug 2016
T100209A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	25 Jan 2013
T460250A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	25 Jan 2013

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer with Non-DEHP Tubing

With TruWave Disposable Pressure Transducer:

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

T001744A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	25 Jan 2013
PX600F	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
PX600I	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
PX600	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
PX600F30	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T001724A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T001631A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T001645A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T100214A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T100215A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T100202A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T330919A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T001758A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T001619A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
PX1X2	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T100212A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T001650A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T001657A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
PX2X3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
T001660A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 Aug 2016
PXVMP260	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	03 Aug 2016
T001691A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	03 Aug 2016
T100209B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	15-Dec-2016
PXVPL0097	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	28 January 2018

Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer with Non-DEHP Tubing

With TruWave Disposable Pressure Transducer:

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

With VAMP:

Class IIa/ Rule10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

PXMK0075	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	26 April 2018
PXVFL0107 (10016118001)	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	23 July 2018
PXMK0108 (10024106001)	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	23 July 2018
T440907B (695176001)	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	23 July 2018
T460241A (695280001)	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	23 July 2018
PXVPZ30008	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	27 February 2020
PXVFL10017 (10019883001)	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	23 March 2020
PXVPL2284 (10022415001)	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	07 April 2020
PXVJL10014 (10035090001)	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	26 May 2020
PXMK10023	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	24 May 2021

Hemodynamic Monitoring Equipment (Temperature Probes)

UMDNS : 13125 Probes, thermometer

GMDN: 37340 Probe, Electronic thermometer, reusable

Class IIa/ Rule 2

Model	Description	Start of CE Marking
9850A	Injectate Temperature Probe	26 October 2004
93522	CO-Set® Injectate Temperature Probe for Edwards Computers	26 June 2000
93523	CO-Set® Injectate Temperature Probe	26 June 2000
93524	CO-Set® Injectate Temperature Probe	04 Feb 2010
93528	CO-Set® Injectate Temperature Probe	04 Feb 2010



Edwards

EC Deklaracja Zgodności

Wytwórca: *Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614, USA*

Przedstawiciel w Europie: *Edwards Lifesciences Services GmbH
Edisonstraße 6
85716 Unterschleißheim, Germany*

Kategoria produktu: *Urządzenia jednorazowego użytku i powiązane akcesoria*

Produkty: ***Jednorazowe materiały do monitorowania hemodynamicznego i powiązane akcesoria***
Kody modeli, nazwy: patrz kolejne strony

Klasyfikacja: *Patrz kolejne strony*
(Zgodnie z załącznikiem 9 MDD)Ścieżka oceny zgodności: Załącznik II (z wyłączeniem Załącznika II.4)

UMDNS / GMDN Nomenklatura: *Patrz kolejne strony*

Stosowane Standardy: *Zobacz listę kontrolną wymagań podstawowych w dokumentacji technicznej*

Początek oznakowania CE: *Patrz kolejne strony*

Niniejszym oświadczamy, że dystrybuowane produkty oznaczone znakiem CE określone powyżej są zgodne z produktami objętymi „Certyfikatem WE” wydanym i dostarczonym przez TÜV zgodnie z Załącznikiem II (z wyłączeniem Załącznika II.4) „Dyrektywy WE”, Rady Dyrektywa 93/42/EWG dotycząca wyrobów medycznych. Niniejsza deklaracja zgodności została wydana na wyłączną odpowiedzialność Edwards Lifesciences LLC. Cała dokumentacja pomocnicza jest przechowywana w siedzibie producenta

Ponadto zapewniamy i deklarujemy, że dystrybuowane produkty oznaczone znakiem CE spełniają postanowienia dyrektywy WE, które mają do nich zastosowanie.

Producent ustanowił i utrzymuje system jakości spełniający wymagania normy EN ISO 13485:2016.

Powyższe dyrektywy i normy są poparte następującymi certyfikatami:

Numer certyfikatu	Ważny do	Wydany przez	Posiadacz Certyfikatu	Siedziba
G1 039555 0198	2024-05-26	TÜV SÜD Product Service	Edwards Lifesciences LLC, Irvine	Edwards Lifesciences LLC, Irvine*

Jednostka Notyfikująca: *TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München, Germany
Identification Number 0123*

Date: _____
Irvine, U.S.A

Aditi Iyengar

Aditi Iyengar

*Senior Manager, Regulatory Affairs
Critical Care*

Digitally signed by Aditi Iyengar
DN: cn=Aditi Iyengar, email=Aditi_Iyengar@edwards.com
Reason: I have reviewed this document
Date: 2022.04.07 16:29:40 -0700

Elementy produktu wprowadzającego (obturator)		
Klasa IIa / Reguła 6		
UMDNS : 11925 Prowadnice		
GMDN : 35094 Prowadnik cewnika		
Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
GW3569I	Multi-Med® Central Venous Infusion Catheter Guidewires	26 czerwca 2000
MO02F7P	Short AVA Obturator	11 września 2000
MO13F7P	Long AVA Obturator	30 października 2008

Elementy produktu wprowadzającego (nasadki obturatora)		
Klasa IIa / Reguła 7		
UMDNS: 16081 kapsli		
GMDN : 42410 Osłona kabla/przewodu/czujnika/sondy, sterylna		
Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
IOBCAP	Obturator Cap	29 maja 2001

Introflex Introduktor		
Klasa IIa / Zasada 7		
UMDNS : 10678 Wprowadzacz cewników		
GMDN: 58865, zestaw wprowadzający do cewnika naczyniowego		
Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
I300F85	Intro-Flex® Percutaneous Sheath Introducers	26 czerwca 2000
I300BF85	Intro-Flex® Percutaneous Sheath Introducers	26 czerwca 2000
I301F6	Intro-Flex® Percutaneous Sheath Introducers	26 czerwca 2000
I301F7	Intro-Flex® Percutaneous Sheath Introducers	26 czerwca 2000
I301F8	Intro-Flex® Percutaneous Sheath Introducers	26 czerwca 2000
I305BF9	Intro-Flex® Percutaneous Sheath Introducers	26 czerwca 2000

Introflex Introduktor		
Klasa IIa / Zasada 7		
UMDNS : 10678 Wprowadzacz cewników		
GMDN: 58865 Zestaw wprowadzający do cewnika naczyniowego		
Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
I350BF85	Intro-Flex® Percutaneous Sheath Introducers	26 czerwca 2000
I351BF7	Intro-Flex® Percutaneous Sheath Introducers	26 czerwca 2000
I355BF9	Intro-Flex® Percutaneous Sheath Introducers	26 czerwca 2000
I451BF6	Intro-Flex® Percutaneous Sheath Introducers	26 czerwca 2000
I451BF8	Intro-Flex® Percutaneous Sheath Introducers	26 czerwca 2000

CO-Set® Plus Zamknięty system wstrzykiwania

Klasa IIa / Zasada 2

UMDNS: 12134 wtryskiwacze, rozcieńczanie termiczne

GMDN: 10615, jednostka rzutu serca z termorozcieńczaniem

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
93600	CO-Set® Plus Closed Injectate System	26 czerwca 2000
93610	CO-Set® Plus Closed Injectate System	26 czerwca 2000

Akcesoria CO-Set®

Klasa IIa / Zasada 2

UMDNS: 13125 Sondy, Termometr

GMDN: 10615 Jednostka rzutu serca do termicznego rozcieńczania

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
93505	CO-Set® Plus Flow-Thru Housing	26 czerwca 2000

Akcesoria CO-Set®

Klasa IIa / Reguła 2

UMDNS: 13929 strzykawek

GMDN: 47017 Strzykawka ogólnego przeznaczenia

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
93650	CO-Set® Plus Syringe	26 czerwca 2000

Urządzenia z dostępem do wielu kanałów

Klasa IIa / Zasada 7

UMDNS: 16615 Zestawy do cewnikowania, Centralna żyła

GMDN: 58865, Zestaw do wprowadzania cewnika naczyniowego

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
M3L85FSI	Multiple Lumen Access Devices	26 czerwca 2000
M3L9FSI	Multiple Lumen Access Devices	26 czerwca 2000

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™

Z jednorazowym przetwornikiem ciśnienia TruWave:

Klasa IIa / Zasada 10

Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);

Z VAMP:

Klasa IIa/ Zasada 10

Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
PX12N	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX1X2	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX200	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™**Z jednorazowym przetwornikiem ciśnienia TruWave:****Klasa IIa / Zasada 10****Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
PX212	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX24N	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX260	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX266C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX272	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX284	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX284AN	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX284R	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX2X2	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX2X2284C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX2X2YB	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX2X3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX36N	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX3X3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX3X3272	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX3X3284C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX3X3AN	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX3X3MT	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX4X4	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX600	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX600F	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX600FP	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	04 kwietnia 2007
PX600F30P	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	04 kwietnia 2007
PX600IP	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™**Z jednorazowym przetwornikiem ciśnienia TruWave:****Klasa IIa / Zasada 10****Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
PX600P	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	04 kwietnia 2007
PX600F30	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX600I	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX600INS	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX601	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX604	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PX604INS	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXAK1568	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXAK2066	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXAK2296	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXAVMP3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXCMK590	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK0010	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	19 czerwca 2014
PXMK0011	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	19 czerwca 2014
PXMK0012	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	19 czerwca 2014
PXMK0013	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	19 czerwca 2014
PXMK0014	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	19 czerwca 2014
PXMK053	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK0666	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK0688	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK0692	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK0695	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK0774	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK0933	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™**Z jednorazowym przetwornikiem ciśnienia TruWave:****Klasa IIa / Zasada 10****Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
PXMK0940	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK0976	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1077	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1140	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1175	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1267	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1300	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1392	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1476	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1479	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1589	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1691	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1736	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1737	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1780	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1805	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1849	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1863	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1876	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK188	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1915	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1940	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1978	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK1997	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™**Z jednorazowym przetwornikiem ciśnienia TruWave:****Klasa IIa / Zasada 10****Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
PXMK2002	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2008	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2011	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2012	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2016	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2041	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2042	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2043	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2047	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2056	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2122	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2128	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2137	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2143	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2144	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2210	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2217	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2257	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2258	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2270	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2274	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2277	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2294	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2318	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™**Z jednorazowym przetwornikiem ciśnienia TruWave:****Klasa IIa / Zasada 10****Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
PXMK2319	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2320	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2326	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2329	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK2330	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK478	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK560	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK7729	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXMK9146	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	22 kwietnia 2013
PXVJ0441	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	22 kwietnia 2013
PXVJ0711	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	22 kwietnia 2013
PXVJ356	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	22 kwietnia 2013
PXVK0363	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVK0387	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVK0388	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVK0398	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVK0438	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVK0458	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVK0670	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVK0738	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVK0755	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVK0797	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVK0965	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVK1001	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™**Z jednorazowym przetwornikiem ciśnienia TruWave:****Klasa IIa / Zasada 10****Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
PXVK1003	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVK1006	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVK1086	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVK268	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVK282	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVMP120	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVMP160	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVMP172	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVMP184	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVMP260	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVMP272	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVMP284	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVMP2X21	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVMP2X31	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVMP3X31	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	22 kwietnia 2013
PXVP0549	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 kwietnia 2013
PXVP0686	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 kwietnia 2013
PXVP0812	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 kwietnia 2013
PXVP0861	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 kwietnia 2013
PXVP0880	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 kwietnia 2013
PXVP0897	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 kwietnia 2013
PXVP0902	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 kwietnia 2013
PXVP0966	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 kwietnia 2013
PXVP1066	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 kwietnia 2013

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™**Z jednorazowym przetwornikiem ciśnienia TruWave:****Klasa IIa / Zasada 10****Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
PXVP1087	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 kwietnia 2013
PXVP2260	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 kwietnia 2013
PXVP2272	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 kwietnia 2013
PXVP2284	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 kwietnia 2013
PXVP2284AT3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 kwietnia 2013
PXVP2284DZ	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 kwietnia 2013
PXVP23X3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 kwietnia 2013
PXVP23X3AT3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 kwietnia 2013
PXVP2X2AT3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	22 kwietnia 2013
T001619A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T001624A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T001631A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T001633A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T001645A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T001650A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T001657A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T001660A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T001670A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T001671A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T001691A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T001702A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T001709A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T001712A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T001713A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™**Z jednorazowym przetwornikiem ciśnienia TruWave:****Klasa IIa / Zasada 10****Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
T001724A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T001737A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T001741A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T001743A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T001744A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T001745A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T001746A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T001758A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T001759A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T001760A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T001765A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T001767A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T001775A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T001786A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T001789B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T001797B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T005002A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T005004A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T005005A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T005021A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	08 maja 2000
T005021G	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	08 maja 2000
T005025A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T005048B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T005049B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™**Z jednorazowym przetwornikiem ciśnienia TruWave:****Klasa IIa / Zasada 10****Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
T005050B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T005052A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T005074A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T005080A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T005086A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T005089A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	08 maja 2000
T005091A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	08 maja 2000
T005093A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T005094A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T100202A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T100209A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T100212A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T100214A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T100215A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T100500A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T100504A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T100671B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T270003B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T270004B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T270900A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T310195A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T310197A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T310682A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T310761C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™**Z jednorazowym przetwornikiem ciśnienia TruWave:****Klasa IIa / Zasada 10****Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
T310762A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T311058A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	08 maja 2000
T312306A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T320137D	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T320139D	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T320161B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T320162C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T320544A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T320563A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T320564A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T320940B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T320941A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T320943A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T320947B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T321570A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T321571A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T321572A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T321573A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T321575A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T321811A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T321811Z	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	17 lipca 2014
T322238A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T322241A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T322242B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™**Z jednorazowym przetwornikiem ciśnienia TruWave:****Klasa IIa / Zasada 10****Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
T322244A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T322247A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T322251A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T322256A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T322515A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T323922D	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T323923A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T323924C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T323930D	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T323931C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T323932C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T325202A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T325306B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T325615A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T326207B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T328201A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T328500A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T330639B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T330831A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T330918A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T330919A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T330V11A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T331E02A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T331F06B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™**Z jednorazowym przetwornikiem ciśnienia TruWave:****Klasa IIa / Zasada 10****Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
T331S05B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T332J01A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T333529A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T333709B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T333710C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T333918A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T333919A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T333C00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T333D00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T333F00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T334041A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T334402A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T334708C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T336546B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T336547B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T336548B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T337003A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T337119B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T337305B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T341210A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T341211A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T341212A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T349301B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T349302A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™**Z jednorazowym przetwornikiem ciśnienia TruWave:****Klasa IIa / Zasada 10****Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
T391312A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T391313A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T391314A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T391608B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T391T00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T391T01A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T395606B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T395705A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T397704A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T397705B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T397708A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T398105B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T398603A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T398807D	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T398808A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T410001Z	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T410114B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T410115C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T413403C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T413405A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T413406A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T413642B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T413670A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T413675A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™**Z jednorazowym przetwornikiem ciśnienia TruWave:****Klasa IIa / Zasada 10****Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
T430023B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T430139A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T430140A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T430142A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T430168A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	08 maja 2000
T430169A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	08 maja 2000
T430177B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T430178B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T430179A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T430180A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T430181A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T430609A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T431108A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T431305A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T431514C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T432104B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T432105A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T432618G	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T432703A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T433201A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T433202B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T433204B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T433801A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T433802A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™**Z jednorazowym przetwornikiem ciśnienia TruWave:****Klasa IIa / Zasada 10****Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
T433803A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T433804Z	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T433806A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T434304A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T434500B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T434501B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T434502B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T440B20B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T440B21A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T440B26B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T440B27B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	24października 2018
T440B28A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T441809C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T441L01A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T441T01C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T442J00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	24 października2018
T443422A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T443952B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	08 maja 2000
T447907A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T449103B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T450217A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T450544A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T450545A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T450553A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	08 maja 2000

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™**Z jednorazowym przetwornikiem ciśnienia TruWave:****Klasa IIa / Zasada 10****Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
T451703A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T460061A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T460225D	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T460235A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T460237A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T460243A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T460249A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T460250A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T461803B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T470411B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	08 maja 2000
T491U01B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T491Y01B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T492011A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T492F02B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T492F02Z	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	17 lipca 2014
T493Y02B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T493Y03B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T494C00B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T495009A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T530116B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T530217B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T530219A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T530219D	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T530223A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™**Z jednorazowym przetwornikiem ciśnienia TruWave:****Klasa IIa / Zasada 10****Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
T530310A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T530317A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T531401A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T531900A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T581201F	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T581203B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T610002A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T770000A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T770001A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T770002A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T770003A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
VMP306PX	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	22 kwietnia 2013
VMP406PX	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	22 kwietnia 2013
VMP426PX	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	22 kwietnia 2013
VMP448PX	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	22 kwietnia 2013
PXAK2253	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer)	22 kwietnia 2013
T001691M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP Plus Blood Management System, LASS)	23 lipca 2013
T005025M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer, LASS)	23 lipca 2013
T001741M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP Adult Blood Management System, LASS)	23 lipca 2013
T005021M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP FLEX Blood Management System, LASS)	23 lipca 2013
T470411M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP Jr. Blood Management System, LASS)	23 lipca 2013

T005050M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP Adult Blood Management System, LASS)	23 lipca 2013
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Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™**Z jednorazowym przetwornikiem ciśnienia TruWave:****Klasa IIa / Zasada 10****Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
T005091M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP FLEX Blood Management System, LASS)	23 lipca 2013
T100671M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP Plus Blood Management System, LASS)	23 lipca 2013
T005089M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP FLEX Blood Management System, LASS)	23 lipca 2013
T311058M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP FLEX Blood Management System, LASS)	23 lipca 2013
T430023M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP Plus Blood Management System, LASS)	23 lipca 2013
T001744M	Pressure Monitoring Set (w/ TruWave Disposable Pressure Transducer and VAMP Adult Blood Management System, LASS)	23 lipca 2013
T490009M	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T490007A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
PXVPL0029	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer) & VAMP Plus)	01 września 2016
PXVPL0030	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer) & VAMP Plus)	01 września 2016
PXVPL0031	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer) & VAMP Plus)	01 września 2016
T100209B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	01 września 2016
PXMK0033	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	15 grudnia 2016
PXVP0034	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer) & VAMP Plus)	15 grudnia 2016
PXVP0035	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer) & VAMP Plus)	15 grudnia 2016
PXVFL0059	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	15 grudnia 2016
PXMK0074	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	11 października 2017
PXVJ0096	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Junior)	11 października 2017
PXVPL20001	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	24 stycznia 2020
PXVKZ30006	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP)	24 stycznia 2020
PXMK10012	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	24 stycznia 2020

VAMP® (system zarządzania krwią)**Klasa IIa / Zasada 2****UMDNS: 10446 Zestawy do pobierania próbek, Krew****GMDN: 31336 Zestaw do pobierania próbek krwi tętnicznej**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
48AVMP	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	22 kwietnia 2013
48VMP106	VAMP Adult (Pressure Monitoring Set/Blood Management System)	25 maja 2016
48VMP120	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	22 kwietnia 2013
48VMP160	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	22 kwietnia 2013
48VMP172	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	03 Dec 2004
48VMP184	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	22 kwietnia 2013
48VMP260	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	22 stycznia 2007
48VMP272	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	03 grudnia 2004
48VMP284	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	22 kwietnia 2013
VJ0990	VAMP Jr (Pressure Monitoring Set/ Blood Management System)	22 kwietnia 2013
VMP306	VAMP Jr (Pressure Monitoring Set/ Blood Management System)	22 kwietnia 2013
VMP406	VAMP Jr (Pressure Monitoring Set/ Blood Management System)	22 kwietnia 2013
VMP426	VAMP Jr (Pressure Monitoring Set/ Blood Management System)	22 kwietnia 2013
VMP448	VAMP Jr (Pressure Monitoring Set/ Blood Management System)	26 czerwca 2000
VP0613	VAMP Plus (Pressure Monitoring Set/ Blood Management System)	22 kwietnia 2013
VP0753	VAMP Plus (Pressure Monitoring Set/ Blood Management System)	22 kwietnia 2013
VP1	VAMP Plus (Pressure Monitoring Set/ Blood Management System)	26 czerwca 2000
VP181Z	VAMP Plus (Pressure Monitoring Set/ Blood Management System)	22 kwietnia 2013
VP2	VAMP Plus (Pressure Monitoring Set/ Blood Management System)	26 czerwca 2000

VAMP® (system zarządzania krwią) — z przewodami/materiałami bez DEHP**Klasa IIa / Zasada 2****UMDNS: 10446 Zestawy do pobierania próbek, Krew****GMDN: 31336 Zestaw do pobierania próbek krwi tętnicznej**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
VMP400	VAMP Needleless Cannula (Pressure Monitoring Set/ Blood Management System)	26 czerwca 2000
VMP600	VAMP Blood Transfer Unit (Pressure Monitoring Set/ Blood Management System)	22 kwietnia 2013
48VMP600	VAMP Blood Transfer Unit (Pressure Monitoring Set/ Blood Management System)	28 lutego 2018
VMP700	VAMP Direct Draw Unit (Pressure Monitoring Set/ Blood Management System)	22 kwietnia 2013
48VMP160	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	03 sierpnia 2016
48VMP260	VAMP Adult (Pressure Monitoring Set/ Blood Management System)	03 sierpnia 2016
VMP306	VAMP Jr (Pressure Monitoring Set/ Blood Management System)	03 sierpnia 2016
VP1	VAMP Plus (Pressure Monitoring Set/ Blood Management System)	03 sierpnia 2016
VP2	VAMP Plus (Pressure Monitoring Set/ Blood Management System)	03 sierpnia 2016
VOPTIMA	VAMP Optima with Z-site + COMBICAP caps, 10-pack	28 lutego 2018
VOPTIMAL	VAMP Optima with LASS + COMBICAP caps, 10-pack	28 lutego 2018
VPL2	VAMP Plus (Blood Management System)	04 czerwca 2019
48VMPL284	VAMP Adult (Blood Management System)	25 lipca 2019

Czujnik FloTrac**Klasa IIa / Zasada 10****UMDNS : 16909 Przetworniki, ciśnieniowe, jednorazowe GMDN : 35927 Przetworniki, ciśnieniowe, jednorazowego użytku****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
MHD6AZ	FloTrac sensor with adult VAMP Kit, 60" tubing	29 sierpnia 2005
MHD6	FloTrac sensor, 60" tubing	29 sierpnia 2005
MHD8	FloTrac sensor, 84" tubing	29 sierpnia 2005
MHD6AZR	FloTrac sensor with adult VAMP Kit, 60" tubing, red stopcock inserts	18 kwietnia 2008
MHD6R	FloTrac sensor, 60" tubing, red stopcock inserts	18 kwietnia 2008
MHD8R	FloTrac sensor, 84" tubing, red stopcock inserts	18 kwietnia 2008
MHD6AZ5	FloTrac sensor, 60" with VAMP, 5 pack	23 grudnia 2008
MHD65	FloTrac sensor, 60", 5 pack	23 grudnia 2008
MHD85	FloTrac sensor, 84", 5 pack	23 grudnia 2008
MHD6S	FloTrac sensor, 60", extra stopcock, 5 pack	23 grudnia 2008
MHD8S	FloTrac sensor, 84", extra stopcock, 5 pack	23 grudnia 2008
MHD6AZA	FloTrac sensor, 60", anesthesia VAMP, 5 pack	23 grudnia 2008

Czujnik FloTrac

Klasa IIa / Zasada 10

UMDNS : 16909 Przetworniki, ciśnieniowe, jednorazowe GMDN : 35927 Przetworniki, ciśnieniowe, jednorazowego użytku

Z VAMP:

Klasa IIa/ Zasada 10

Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
MHD6AZR5	FloTrac sensor, 60", VAMP, red caps, 5 pack	23 grudnia 2008
MHD6R5	FloTrac sensor, 60", red caps, 5 pack	23 grudnia 2008
MHD8R5	FloTrac sensor, 84", red caps, 5 pack	23 grudnia 2008
MHD8C503	FloTrac sensor, 84", w/ TruWave DPT	11 września 2017

Czujnik FloTrac/FloTrac IQ/Acumen IQ/VolumeView — z przewodami bez DEHP

Klasa IIa / Zasada 10

UMDNS : 16909 Przetworniki, ciśnieniowe, jednorazowe GMDN : 35927 Przetworniki, ciśnieniowe, jednorazowego użytku

Z VAMP:

Klasa IIa/ Zasada 10

Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)

Kod Modelu	Nazwa	Data pierwszego oznakowania CE
VLV8R5	VolumeView Sensor	03 sierpnia 2016
MHD6R	60in FloTrac Standalone	03 sierpnia 2016
MHD6AZR	60in FloTrac with Adult Vamp	03 sierpnia 2016
MHD6AZR5	60in FloTrac with Adult Vamp	03 sierpnia 2016
MHD8R	84in FloTrac Standalone	03 sierpnia 2016
MHD6R5	60in FloTrac Standalone	03 sierpnia 2016
MHD8R5	84in FloTrac Standalone	03 sierpnia 2016
MHDQ8R5	FloTrac IQ Sensor, 84", Red Caps, 5 Pack	09 stycznia 2017
FTAFM8R5	FloTrac IQ Sensor, For AFM 84" / 213cm, 5 Pack With RedCaps	16 marca 2017
HSFTQ8R5	FloTrac IQ Sensor for HemoSphere 84"/213CM 5-Pack withRed Caps	22 grudnia 2017
MHD8VZ	FloTrac sensor + IV Set + VAMP Optima with Z-Site + COMBICAP caps, single pack	22 grudnia 2017
MHDQ8VZ	FloTrac IQ sensor + IV Set + VAMP Optima with Z-site +COMBICAP caps, single pack	22 grudnia 2017
MHD8VZ5	FloTrac sensor + IV Set + VAMP Optima with Z-site + COMBICAP caps, 5-pack	22 grudnia 2017
MHDQ8VZ5	FloTrac IQ sensor + IV Set + VAMP Optima with Z-site +COMBICAP caps, 5-pack	22 grudnia 2017
MHD8VRL	FloTrac sensor + IV Set + VAMP Optima with LASS + COMBICAP caps + red striped tubing, single pack	22 grudnia 2017
MHDQ8VRL	FloTrac IQ sensor + IV Set + VAMP Optima with LASS + COMBICAP caps + red striped tubing, single pack	22 grudnia 2017
MHD8VRL5	FloTrac sensor + IV Set + VAMP Optima with LASS + COMBICAP caps + red striped tubing, 5-pack	22 grudnia 2017
MHDQ8VRL5	FloTrac IQ sensor + IV Set + VAMP Optima with LASS + COMBICAP caps + red striped tubing, 5-pack	22 grudnia 2017

Czujnik FloTrac/FloTrac IQ/Acumen IQ/VolumeView — z przewodami bez DEHP**Klasa IIa / Zasada 10****UMDNS : 16909 Przetworniki, ciśnieniowe, jednorazowe GMDN : 35927 Przetworniki, ciśnieniowe, jednorazowego użytku****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
MHD8VZTW	FloTrac sensor + IV Set + TruWave DPT + VAMP Optima with Z-site + COMBICAP caps + blue striped tubing, 5-pack	22 grudnia 2017
MHDQ8VZTW	FloTrac IQ sensor + IV Set + TruWave DPT + VAMP Optima with Z-site + COMBICAP caps + blue striped tubing, 5-pack	22 grudnia 2017
MHDQ8VLTW	FloTrac IQ sensor + IV Set + TruWave DPT + VAMP Optima with LASS + COMBICAP caps + red striped tubing + blue striped tubing, 5-pack	22 grudnia 2017
MHD8VLTW	FloTrac sensor + IV Set + TruWave DPT + VAMP Optima with LASS + COMBICAP caps + red striped tubing + blue striped tubing, 5-pack	22 grudnia 2017
MHD8VRZ5	FloTrac sensor + IV Set + VAMP Optima with Z-site + COMBICAP caps + red striped tubing, 5-pack	25 października 2018
MHD8VRZTW	FloTrac sensor + IV Set + TruWave DPT + VAMP Optima with Z-site, + COMBICAP caps + red striped tubing + blue striped tubing, 5-pack	25 października 2018
AIQS6R	Acumen IQ Sensor, 60", Red Caps	13 grudnia 2018
AIQS6R5	Acumen IQ Sensor, 60", Red Caps, 5-pack	13 grudnia 2018
AIQS8R	Acumen IQ Sensor, 84", Red Caps	13 grudnia 2018
AIQS8R5	Acumen IQ Sensor, 84", Red Caps, 5-pack	13 grudnia 2018
AIQS6AZR	Acumen IQ Sensor with VAMP System 60" with Red Cap	21 maja 2019
AIQS6AZR5	Acumen IQ Sensor W/ VAMP Adult 60" with Red Cap, 5-pack	21 maja 2019
AIQSAFM8R5	Acumen IQ Sensor for use with Assisted Fluid Management software feature, 5-pack	21 maja 2019
AIQS6S	Acumen IQ, 60" / 152CM (Shield)	04 czerwca 2019
AIQS8C503	Acumen IQ, 84" / 213CM Double Line Kit - No VAMP	04 czerwca 2019
AIQS8S	Acumen IQ, 84" / 213CM (Shield)	04 czerwca 2019
AIQS8S102	Acumen IQ, 84" / 213CM Double Line Kit -- With VAMP	04 czerwca 2019

Czujnik FloTrac IQ/Acumen IQ**Klasa IIa / Reguła 10UMDNS: 16909 Przetworniki, ciśnienie, jednorazowe GMDN: 35927 Przetwornik, ciśnienie, jednorazowego użytku****Z VAMP:****Klasa IIa/ Zasada 10****Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)**

Kod Modelu	Nazwa	Data pierwszego oznakowania CE
MHDQ6AZ	FloTrac IQ Sensor with Adult VAMP Kit, 60" tubing	30 września 2016
MHDQ6	FloTrac IQ Sensor, 60" Tubing	30 września 2016
MHDQ8	FloTrac IQ Sensor, 84" Tubing	30 września 2016

Czujnik FloTrac IQ/Acumen IQ

Klasa IIa / Reguła 10UMDNS: 16909 Przetworniki, ciśnienie, jednorazowe GMDN: 35927 Przetwornik, ciśnienie, jednorazowego użytku

Z VAMP:

Klasa IIa/ Zasada 10

Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
MHDQ6AZR	FloTrac IQ Sensor with Adult VAMP Kit, 60" Tubing, Red Stopcock Inserts	30 sierpnia 2016
MHDQ6AZ5	FloTrac IQ Sensor, 60" with VAMP, 5 pack	30 sierpnia 2016
MHDQ85	FloTrac IQ Sensor, 84", 5 pack	30 sierpnia 2016
MHDQ8R5	FloTrac IQ Sensor, 84", red caps, 5 pack	30 sierpnia 2016
MHDQ65	FloTrac IQ Sensor 60"/152CM	16 marca 2017
MHDQ6AZA	FloTrac IQ Sensor with VAMP 60"/152CM	16 marca 2017
MHDQ6AZR5	FloTrac IQ Sensor with VAMP ADULT 60"/152CM 5-Pack with Red Cap	16 marca 2017
MHDQ6C502	FloTrac IQ Sensor 60"/152CM Double Line Kit – with VAMP	16 marca 2017
MHDQ6R	FloTrac IQ Sensor 60"/152CM with Red Cap	16 marca 2017
MHDQ6R5	FloTrac IQ Sensor 60"/152CM 5-Pack with Red Cap	16 marca 2017
MHDQ6S	FloTrac IQ Sensor 60"/152CM (Shield)	16 marca 2017
MHDQ8C503	FloTrac IQ Sensor 84" / 213CM Double Line Kit – No VAMP	16 marca 2017
MHDQ8R	FloTrac IQ Sensor 84" / 213CM with Red Cap	16 marca 2017
MHDQ8S	FloTrac IQ Sensor 84" / 213CM (Shield)	16 marca 2017
MHDQ8S102	FloTrac IQ Sensor 84" / 213CM Double Line Kit – With VAMP	16 marca 2017
FTAFM8R5	FloTrac IQ Sensor for AFM 84" / 213CM 5-Pack with Red Cap	16 marca 2017
HSFTQ8R5	FloTrac IQ Sensor for HemoSphere 84"/213CM 5-Pack with Red Caps	22 listopada 2017
AIQS6	Acumen IQ Sensor, 60"	13 grudnia 2018
AIQS65	Acumen IQ Sensor, 60", 5-pack	13 grudnia 2018
AIQS6R	Acumen IQ Sensor, 60", Red Caps	13 grudnia 2018
AIQS6R5	Acumen IQ Sensor, 60", Red Caps, 5-pack	13 grudnia 2018
AIQS8	Acumen IQ Sensor, 84"	13 grudnia 2018
AIQS85	Acumen IQ Sensor, 84", 5-pack	13 grudnia 2018
AIQS8R	Acumen IQ Sensor, 84", Red Caps	13 grudnia 2018
AIQS8R5	Acumen IQ Sensor, 84", Red Caps, 5-pack	13 grudnia 2018
AIQS6AZ	Acumen IQ with VAMP System 60" / 152CM	21 maja 2019
AIQS6AZ5	Acumen IQ W/ VAMP Adult 60"/152cm 5-Pack	21 maja 2019
AIQS6AZA	Acumen IQ with VAMP System 60" / 152CM	21 maja 2019

Czujnik FloTrac IQ/Acumen IQ

Klasa IIa / Reguła 10UMDNS: 16909 Przetworniki, ciśnienie, jednorazowe GMDN: 35927 Przetwornik, ciśnienie, jednorazowego użytku

Z VAMP:

Klasa IIa/ Zasada 10

Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
AIQS6AZR	Acumen IQ with VAMP System 60" / 152CM with Red Cap	21 maja 2019
AIQS6AZR5	Acumen IQ W/ VAMP Adult 60"/152cm 5-Pack with Red Cap	21 maja 2019
AIQS6C502	Acumen IQ, 60" / 152CM Double Line Kit with VAMP	21 maja 2019
AIQS6S	Acumen IQ, 60" / 152CM (Shield)	21 maja 2019
AIQS8C503	Acumen IQ, 84" / 213CM Double Line Kit - No VAMP	21 maja 2019
AIQSAFM8R5	Acumen IQ, for use with Assisted Fluid Management software feature	21 maja 2019
AIQS8S	Acumen IQ, 84" / 213CM (Shield)	21 maja 2019
AIQS8S102	Acumen IQ, 84" / 213CM Double Line Kit -- With VAMP	21 maja 2019

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™ z przewodami bez DEHP

Z jednorazowym przetwornikiem ciśnienia TruWave:

Klasa IIa / Zasada 10

Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);

Z VAMP:

Klasa IIa/ Zasada 10

Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
T001670A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	25 stycznia 2013
T001671A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	25 stycznia 2013
T001624A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	07 czerwca 2013
T001775A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	07 czerwca 2013
T100671B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	07 czerwca 2013
T460061A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	07 czerwca 2013
T460235A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	07 czerwca 2013
T461803B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	07 czerwca 2013

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™ z przewodami bez DEHP

Z jednorazowym przetwornikiem ciśnienia TruWave:

Klasa IIa / Zasada 10

Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);

Z VAMP:

Klasa IIa/ Zasada 10

Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)

T470411B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	07 czerwca 2013
T005074A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	07 czerwca 2013
T310844A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	30 września 2015
T310845A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	30 września 2015
T310846A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	30 września 2015
T310847A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	30 września 2015
T451702A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T451703A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	08 maja 2000
T001673A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T434303A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	08 maja 2000
T001725A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T450552C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	08 maja 2000
T001658A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T433803A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	08 maja 2000
T320941C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	15 października 2015
T320943B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	15 października 2015
T331U03C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	15 października 2015
PXVJ050M	LASS Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr) with Non-DEHP Tubing	15 października 2015
T310761C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
PX2X2YB	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T333919A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T333C00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T333F00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T330831A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™ z przewodami bez DEHP

Z jednorazowym przetwornikiem ciśnienia TruWave:

Klasa IIa / Zasada 10

Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);

Z VAMP:

Klasa IIa/ Zasada 10

Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)

PX284AN	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T331F06B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T333D00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T334708C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T332J01A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T331E02A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T334041A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T334402A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T337119B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T330918A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T331S05B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T333918A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T321571A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T333709B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T323932C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T531401A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T330V11A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T337305B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T333710C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T336546B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	03 sierpnia 2016
T336547B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	03 sierpnia 2016
T336548B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	03 sierpnia 2016
T100209A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	25 stycznia 2013
T460250A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	25 stycznia 2013

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™ z przewodami bez DEHP

Z jednorazowym przetwornikiem ciśnienia TruWave:

Klasa IIa / Zasada 10

Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);

Z VAMP:

Klasa IIa/ Zasada 10

Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)

T001744A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	25 stycznia 2013
PX600F	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
PX600I	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
PX600	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
PX600F30	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T001724A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T001631A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T001645A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T100214A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T100215A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T100202A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T330919A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T001758A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T001619A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
PX1X2	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T100212A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T001650A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T001657A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
PX2X3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
T001660A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	03 sierpnia 2016
PXVMP260	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	03 sierpnia 2016
T001691A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	03 sierpnia 2016
T100209B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	15 grudnia 2016
PXVPL0097	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	28 stycznia 2018

Zestaw/zestaw do monitorowania ciśnienia z jednorazowym przetwornikiem ciśnienia TruWave™ z przewodami bez DEHP

Z jednorazowym przetwornikiem ciśnienia TruWave:

Klasa IIa / Zasada 10

Kod UMDNS: 16909, Przetwornik, ciśnienie, jednorazowego użytku (kod GMDN: 35927);

Z VAMP:

Klasa IIa/ Zasada 10

Kod UMDNS: 10446, zestaw do pobierania krwi (kod GMDN: 31336)

PXMK0075	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	26 kwietnia 2018
PXVFL0107 (10016118001)	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	23 lipca 2018
PXMK0108 (10024106001)	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	23 lipca 2018
T440907B (695176001)	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	23 lipca 2018
T460241A (695280001)	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	23 lipca 2018
PXVPZ30008	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	27 lutego 2020
PXVFL10017 (10019883001)	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Flex)	23 marca 2020
PXVPL2284 (10022415001)	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	07 kwietnia 2020
PXVJL10014 (10035090001)	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Jr)	26 maja 2020
PXMK10023	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	24 maja 2021

Sprzęt do monitorowania hemodynamicznego (sondy temperatury)

UMDNS: 13125 Sondy, termometr

GMDN: 37340 Sonda, termometr elektroniczny, wielokrotnego użytku Klasa IIa/Zasada 2

Kod Modelu	Nazwa	Data pierwszego zastosowania oznakowania CE
9850A	Injectate Temperature Probe	26 października 2004
93522	CO-Set® Injectate Temperature Probe for Edwards Computers	26 czerwca 2000
93523	CO-Set® Injectate Temperature Probe	26 czerwca 2000
93524	CO-Set® Injectate Temperature Probe	04 lutego 2010
93528	CO-Set® Injectate Temperature Probe	04 lutego 2010



Product Service

Certyfikat EC

System Zapewnienia Jakości w Zakresie Produkcji

Dyrektywa 93/42/EEC dotycząca urządzeń medycznych, Aneks II, wykluczając ustęp 4 (Urządzenia klasy IIa, IIb lub III)

Nr: G1 039555 0198 Rev.00

Producent:

Edwards Lifesciences LLC

One Edwards Way

Irvine, CA 92614

USA

Kategoria Produktu:

- Sprzęt do hemodynamicznego monitorowania
- Sprzęt do hemodynamicznego monitorowania jednorazowego użytku
- Urządzenia medyczne stosowane do diagnozowania i leczenia choroby wieńcowej
- Urządzenia medyczne stosowane do diagnozowania i leczenia choroby obwodowo naczyniowej
- Urządzenia medyczne stosowane do leczenia chorób serca i centralnego układu krążenia zgodnie z listami kontrolnymi

Organ certyfikacyjny TÜV Product Service GmbH oświadcza, że wyżej wymieniony producent wdrożył system zapewnienia jakości w odniesieniu do projektowania, produkcji i ostatecznej kontroli wymienionych powyżej urządzeń / Kategorii urządzeń zgodnie z Aneksem II, Dyrektywy dotyczącej urządzeń medycznych. Niniejszy system zapewnienia jakości odpowiada wymaganiom Dyrektywy i podlega okresowym kontrolom. Do wprowadzenia do sprzedaży produktów klasy III wymagany jest dodatkowy Aneks II (4) – certyfikat. Zobacz również adnotacje na rewersie.

Raport nr:

72150159

Ważny od:

2019-10-29

Data ważności:

2024-05-26

Christoph Dicks
Head of Certification/Notified Body

Data, 2019-10-29

TÜV PRODUCT SERVICE GmbH jest Organem Certyfikacyjnym zgodnie z Dyrektywą Rady 93/42/EEC dotycząca urządzeń medycznych o numerze identyfikacyjnym: 0123

Strona 1 z 2



Product Service

Certyfikat EC

System Zapewnienia Jakości w Zakresie Produkcji

Dyrektywa 93/42/EEC dotycząca urządzeń medycznych, Aneks II, wykluczając ustęp 4
(Urządzenia klasy IIa, IIb lub III)

Nr: G1 039555 0198 Rev.00

Wytwórca (y):

Edwards Lifesciences Technology Sàrl
State Rd. 402, Km 1.4, Industrial Park, 00610-1577 Añasco,
PUERTO RICO USA

Edwards Lifesciences AG, Parue Industrial Itabo
Km 18.5 CARR.Sanchez, Haina, San Cristobal,
Republika Dominikany

Edwards Lifesciences LLC
One Edwards Way, Irvine, CA 92614, USA

ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFIKAT ◆ СЕРТИФИКАТ ◆ 認証証書 ◆ CERTIFIKAT ◆ ZERTIFIKAT ◆



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zlg.de
 ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
 Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
 (Devices in Class IIa, IIb or III)

No. G1 039555 0198 Rev. 00

Facility(ies):

Edwards Lifesciences AG, Parque Industrial Itabo
 Km 18.5 CARR.Sanchez, Haina, San Cristobal, DOMINICAN
 REPUBLIC

Edwards Lifesciences Technology Sàrl
 State Road 402, Km 1.4, Industrial Park, 00610-1577 Añasco,
 PUERTO RICO USA

Edwards Lifesciences LLC
 One Edwards Way, Irvine CA 92614, USA

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Formularz dla podmiotów / Form for organizations

A. Identyfikacja właściwego organu / Identification of the Competent Authority	
1.001 Kod / Code PL/CA01	
1.002 Nazwa w języku miejscowym - po polsku / Name in local language - in Polish Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych	
1.003 Nazwa po angielsku / Name in English The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products	
1.004 Kod kraju / Country code PL	1.005 Kod pocztowy i miasto / Postal code and city
1.006 Ulica, nr / Street, no.	1.007 Telefon / Phone +48 22 4921100

Proszę wypełniać tylko pola z białym tłem / Please fill in fields with a white background only

B. Identyfikacja zgłoszenia lub powiadomienia / Identification of notification	
1.008 Data wpływu / Date of notification	1.009 Numer referencyjny / Reference number
1.010 Rodzaj zgłoszenia lub powiadomienia / Notification type	
<input checked="" type="checkbox"/> 1. Pierwsze dla wyrobu / First for device <input type="checkbox"/> 2. Zmiana danych podmiotu / Change of entity details <input type="checkbox"/> 3. Zmiana danych wyrobu / Change of device details	
1.011 W przypadku zmiany dotyczącej podmiotu proszę wskazać dane ulegające zmianie In case of change of entity details please indicate the data being changed	
1.012 Status podmiotu dokonującego niniejszego zgłoszenia lub powiadomienia / Status of the organization making this notification	
<input type="checkbox"/> W - Wytwórca (Producent) / Manufacturer <input type="checkbox"/> A - Autoryzowany przedstawiciel (Upoważniony przedstawiciel) / Authorized representative <input type="checkbox"/> I - Importer / Importer <input checked="" type="checkbox"/> D - Dystrybutor / Distributor <input type="checkbox"/> Z - Podmiot zestawiający system lub zestaw zabiegowy / Organization assembling system or procedure pack <input type="checkbox"/> S - Podmiot sterylizujący wyrób medyczny, system lub zestaw zabiegowy / Organization sterilizing medical device, system or procedure pack <input type="checkbox"/> O - Świadczeniodawca wykonujący ocenę działania (badanie działania) / Organization carrying out performance evaluation <input type="checkbox"/> L - Laboratorium wytwarzające na swój użytek wyrób IVD / Laboratory produced in home IVD device <input type="checkbox"/> DL - Podmiot wykonujący działalność leczniczą / Entity performing medical activity <input type="checkbox"/> IZ - Instytucja zdrowia publicznego / Health institution <input type="checkbox"/> P - Podmiot, który używa wyrobów do działalności gospodarczej lub zawodowej / Entity that uses products for business or professional activity	

ID: 4337 6982 1969

WM1_FL_1.4

Urząd Rejestracji Produktów Leczniczych,
Wyrobów Medycznych i Produktów Biobójczych
Kancelaria Główna

2022 - 12 - 02 1 / 3

Nr
 Liczba załącz. i kół
 Podpis przyjmującego *Chruściel* -6-

C. Identyfikacja wytwórcy (producenta) / Identification of the manufacturer	
1.013 Numer referencyjny / Reference number	1.014 Kod kraju / Country code FR
1.015 Nazwa wytwórcy (producenta), pełna / Name of the manufacturer, in full Nissha Medical Technologies SAS	
1.016 Nazwa wytwórcy (producenta), skrócona / Name of the manufacturer, abbreviated	
1.017 Miasto / City Cergy	1.018 Kod pocztowy / Postal code 95800
1.019 Ulica, nr / Street, no. 23-25 Boulevard de la Paix	1.020 Skrytka pocztowa / PO Box
Osoba do kontaktu / Contact person	
1.021 Imię i nazwisko / Full name Arnaud Cochetoux	1.022 Telefon / Phone +33139726666
1.023 E-mail HS.Info@NisshaMedical.com	1.024 Faks / Fax +33139726161

D. Identyfikacja autoryzowanego przedstawiciela (upoważnionego przedstawiciela) / Identification of the authorized representative	
1.025 Numer referencyjny / Reference number	1.026 Kod kraju / Country code
1.027 Nazwa autoryzowanego przedstawiciela (upoważnionego przedstawiciela), pełna / Name of the authorized representative, in full	
1.028 Nazwa autoryzowanego przedstawiciela (upoważnionego przedstawiciela), skrócona / Name of the authorized representative, abbreviated	
1.029 Miasto / City	1.030 Kod pocztowy / Postal code
1.031 Ulica, nr / Street, no.	1.032 Skrytka pocztowa / PO Box
Osoba do kontaktu / Contact person	
1.033 Imię i nazwisko / Full name	1.034 Telefon / Phone
1.035 E-mail	1.036 Faks / Fax

E. Identyfikacja ... / Identification of the ...		1.037 <input type="checkbox"/> I - ... importera / ... importer <input checked="" type="checkbox"/> D - ... dystrybutora / ... distributor
1.038 Numer referencyjny / Reference number	1.039 Kod kraju / Country code PL	
1.040 Nazwa importera lub dystrybutora, pełna / Name of the importer or distributor, in full EDWARDS LIFESCIENCES POLAND SP. Z O.O.		
1.041 Nazwa importera lub dystrybutora, skrócona / Name of the importer or distributor, abbreviated		
1.042 Miasto / City WARSZAWA	1.043 Kod pocztowy / Postal code	
1.044 Ulica, nr / Street, no. ALEJE JEROZOLIMSKIE 94	1.045 Skrytka pocztowa / PO Box	
Osoba do kontaktu / Contact person		
1.046 Imię i nazwisko / Full name Barbara Szostyk	1.047 Telefon / Phone 22 256 38 80	
1.048 E-mail Barbara_Szostyk@edwards.com	1.049 Faks / Fax 22 256 38 88	

F. Identyfikacja ... / Identification of the organization ...	
<input type="checkbox"/> Z - ... podmiotu zestawiającego system lub zestaw zabiegowy / ... assembling system or procedure pack <input type="checkbox"/> S - ... podmiotu sterylizującego wyrób medyczny, system lub zestaw zabiegowy / ... sterilizing medical device, system or procedure pack <input type="checkbox"/> O - ... Świadczeniodawcy wykonującego ocenę działania (badanie działania) / ... carrying out performance evaluation 1.050 <input type="checkbox"/> L - ... laboratorium wytwarzające na swój użytek wyrób IVD / Laboratory produced in home IVD device <input type="checkbox"/> DL - ... podmiot wykonujący działalność leczniczą / Entity performing medical activity <input type="checkbox"/> IZ - ... instytucja zdrowia publicznego / Health institution <input type="checkbox"/> P - ... podmiot, który używa wyrobów do działalności gospodarczej lub zawodowej / Entity that uses products for business or professional	
1.051 Numer referencyjny / Reference number	1.052 Kod kraju / Country code
1.053 Nazwa podmiotu, pełna / Name of the organization, in full	
1.054 Nazwa podmiotu, skrócona / Name of the organization, abbreviated	
1.055 Miasto / City	1.056 Kod pocztowy / Postal code
1.057 Ulica, nr / Street, no.	1.058 Skrytka pocztowa / PO Box
Osoba do kontaktu / Contact person	
1.059 Imię i nazwisko / Full name	1.060 Telefon / Phone
1.061 E-mail	1.062 Faks / Fax
G. Identyfikacja pełnomocnika działającego w imieniu podmiotu dokonującego zgłoszenia lub powiadomienia Identification of the person acting as proxy for the organization making this notification	
Wypełnia pełnomocnik ustanowiony na mocy art. 33 KPA lub art. 38 ust. 1 ustawy o CEIDG i Punkcie Informacji dla Przedsiębiorcy To be filled in by person acting as proxy in accordance with art. 33 of the Polish Code of Administrative Procedure or art. 45 par. 1 of CEIDG Act	
1.063 Imię i nazwisko / Full name Barbara Szostyk	
1.064 Miasto / City WARSZAWA	1.065 Kod pocztowy / Postal code 00-807
1.066 Ulica, nr / Street, no. ALEJE JEROZOLIMSKIE 94	1.067 Skrytka pocztowa / PO Box
1.068 Telefon / Phone 22 256 38 80	1.069 Faks / Fax
H. Liczba wyrobów objętych tym zgłoszeniem lub powiadomieniem / Number of devices covered by this notification	
Proszę podać właściwe liczby lub zero, jeśli nie dołączono danego typu formularza Please provide proper numbers or zero if there are no attached forms of given type	
1.070 Liczba dołączonych Załączników nr 2 / Number of attached forms no. 2	0
1.071 Liczba dołączonych Załączników nr 3 / Number of attached forms no. 3	0
1.072 Liczba wyrobów wymienionych w dołączonych Załącznikach nr 4 / Number of devices listed in attached forms no. 4	1

Potwierdzam, że powyższe informacje są poprawne według mojej najlepszej wiedzy.

I affirm that the information given above is correct to the best of my knowledge.

Miasto / City WARSZAWA

Data / Date 2024-11-18
Barbara Sciences Poland Sp. z o.o.
 Specjalista ds. zamówień publicznych

Nazwisko / Name Barbara Szostyk

Podpis / Signature Barbara Szostyk
 Pełnomocnik

Wykaz wyrobów objętych powiadomieniem

List of devices covered by this notification

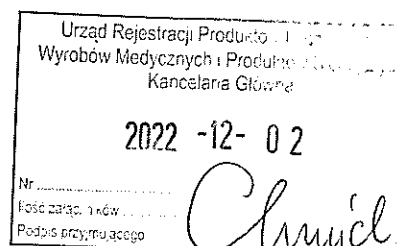
Proszę wypełniać tylko pola z białym tłem / Please fill in fields with a white background only

A. Identyfikacja powiadomienia / Identification of notification	
4.001 Numer kolejny Załącznika nr 4 w obrębie tego powiadomienia 1 Ordinal number of form no. 4 within this notification	4.002 Numer referencyjny Załącznika nr 1 / Reference number of form no. 1
B. Wykaz wyrobów / List of devices	
4.003 Nr referencyjny / Ref. no	4.004 Nazwa handlowa wyrobu / Trade name of device (1), 2)
	CABLE COMPATIBLE EDWARDS REF: 8960PBL1, 896019001, 896004001, 8960SMPNL, 8960AXPNL, 896083L1B, 896083L1BS, 896083L1BS, 896083L2B, 896083L2BS, 896083L3B, 896083L3BS, 896083L4B, 896135001, 8960MSEPNL, 896038001, 896007011, 896508L1, 896508L2, 8960DS001
	CABLE COMPATIBLE EDWARDS REF: 8960JTL1, 8960JLL1, 8960GEPNL, 8960JSPNL, 8960SPPNL, 8960CML1, 8960CML1BS, 896020001, 896016011, 896031001, 896056001, 896507001, 896507001S, 896507L2, 896507L3, 896507L4, 8960AZPNL, 896600PNL, 896025001, 896020001
	CABLE COMPATIBLE EDWARDS REF: 896012013, 896012L2, 896012L3, 8960SCEPNL, 8960SCPMLS, 896079011, 8960CKPNL, 8960CKL2, 8960CKL3, 8960WBL1, 896021001, 896021001S, 896021L2, 896021L3, 896088011, 896080001, 896080001S, 896080001S

Potwierdzam, że powyższe informacje są poprawne według mojej najlepszej wiedzy.
I affirm that the information given above is correct to the best of my knowledge.

Miasto / City WARSZAWA Data / Date 2022-11-30
 Nazwisko / Name Barbara Szostyk Podpis / Signature Barbara Szostyk
 Edwards-Lifesciences Poland Sp. z o.o.
 Specjalista ds. zamówień publicznych
 Pełnomocnik

- 1) Wyroby różniące się nazwą handlową, typem, modelem, wersją wykonania, wersją oprogramowania, rozmiarem, kształtem lub wymiarami można uznać za jeden wyrób i zamieścić w jednym powiadomieniu, jeżeli są lub mają:
- jednego wytwórcę,
 - jednego autoryzowanego przedstawiciela, jeżeli ich wytwórca nie ma siedziby lub miejsca zamieszkania w państwie członkowskim,
 - jeden, wspólny, krótki opis wyrobu i jego przewidziane zastosowanie,
 - jedną, możliwie najbardziej szczegółową nazwę rodzajową,
 - jeden kod wyrobu według Globalnej Nomenklatury Wyrobów Medycznych albo innej uznanej nomenklatury wyrobów medycznych,
 - tę samą klasyfikację albo kwalifikację,
 - wspólną ocenę zgodności wykonaną z użyciem tych samych procedur oceny zgodności,
 - wspólny certyfikat zgodności lub wspólne certyfikaty zgodności, jeżeli w ocenie ich zgodności brała udział jednostka notyfikowana,
 - jeden numer referencyjny w bazie EUDAMED i jedną nazwę handlową w języku polskim albo jedną nazwę handlową w języku angielskim.
- 2) Systemy lub zestawy zabiegowe o tym samym przeznaczeniu, zestawione przez ten sam podmiot i zawierające te same wyroby medyczne, które w poszczególnych systemach lub zestawach zabiegowych występują w różnych ilościach lub różnią się nazwą handlową, typem, modelem, wersją wykonania, wersją oprogramowania, rozmiarem, kształtem lub wymiarami można uznać za jeden system lub zestaw zabiegowy, jeżeli odpowiadające sobie wyroby medyczne w poszczególnych systemach lub zestawach zabiegowych mogą być uznane za jeden wyrób zgodnie z pkt 1.



Formularz dla podmiotów / Form for organizations

A. Identyfikacja właściwego organu / Identification of the Competent Authority	
1.001 Kod / Code PL/CA01	
1.002 Nazwa w języku miejscowym - po polsku / Name in local language - In Polish Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych	
1.003 Nazwa po angielsku / Name in English The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products	
1.004 Kod kraju / Country code PL	1.005 Kod pocztowy i miasto / Postal code and city
1.006 Ulica, nr / Street, no.	1.007 Telefon / Phone +48 22 4921100

Proszę wypełniać tylko pola z białym tłem / Please fill in fields with a white background only

B. Identyfikacja zgłoszenia lub powiadomienia / Identification of notification	
1.008 Data wpływu / Date of notification	1.009 Numer referencyjny / Reference number
1.010 Rodzaj zgłoszenia lub powiadomienia / Notification type	
<input checked="" type="checkbox"/> 1. Pierwsze dla wyrobu / First for device <input type="checkbox"/> 2. Zmiana danych podmiotu / Change of entity details <input type="checkbox"/> 3. Zmiana danych wyrobu / Change of device details	
1.011 W przypadku zmiany dotyczącej podmiotu proszę wskazać dane ulegające zmianie In case of change of entity details please indicate the data being changed	
1.012 Status podmiotu dokonującego niniejszego zgłoszenia lub powiadomienia / Status of the organization making this notification	
<input type="checkbox"/> W - Wytwórca / Manufacturer <input type="checkbox"/> A - Autoryzowany przedstawiciel / Authorized representative <input type="checkbox"/> I - Importer / Importer <input checked="" type="checkbox"/> D - Dystrybutor / Distributor <input type="checkbox"/> Z - Podmiot zestawiający system lub zestaw zabiegowy / Organization assembling system or procedure pack <input type="checkbox"/> S - Podmiot sterylizujący wyrób medyczny, system lub zestaw zabiegowy / Organization sterilizing medical device, system or procedure pack <input type="checkbox"/> O - Świadczeniodawca wykonujący ocenę działania / Organization carrying out performance evaluation <input type="checkbox"/> L - Laboratorium wytwarzające na swój użytek wyrób IVD / Laboratory produced in home IVD device	

Urząd Rejestracji Produktów Leczniczych,
Wyrobów Medycznych i Produktów Biobójczych
Kancelaria Główna

2019-05-24

Nr
 Ilość załączników Strona - Page 1 / 3
 Podpis przyjmującego -9-

C. Identyfikacja wytwórcy / Identification of the manufacturer

1.013 Numer referencyjny / Reference number	1.014 Kod kraju / Country code US
1.015 Nazwa wytwórcy, pełna / Name of the manufacturer, in full EDWARDS LIFESCIENCES, LLC	
1.016 Nazwa wytwórcy, skrócona / Name of the manufacturer, abbreviated	
1.017 Miasto / City IRVINE	1.018 Kod pocztowy / Postal code 92614
1.019 Ulica, nr / Street, no. ONE EDWARDS WAY	1.020 Skrytka pocztowa / PO Box
Osoba do kontaktu / Contact person	
1.021 Imię i nazwisko / Full name MOMCHIL BLAGOEV	1.022 Telefon / Phone
1.023 E-mail MOMCHIL_BLAGOEV@EDWARDS.COM	1.024 Faks / Fax

D. Identyfikacja autoryzowanego przedstawiciela / Identification of the authorized representative

1.025 Numer referencyjny / Reference number	1.026 Kod kraju / Country code DE
1.027 Nazwa autoryzowanego przedstawiciela, pełna / Name of the authorized representative, in full EDWARDS LIFESCIENCES SERVICES GMBH	
1.028 Nazwa autoryzowanego przedstawiciela, skrócona / Name of the authorized representative, abbreviated	
1.029 Miasto / City UNTERSCHLEISSHEIM	1.030 Kod pocztowy / Postal code 85716
1.031 Ulica, nr / Street, no. EDISONSTRASSE 6	1.032 Skrytka pocztowa / PO Box
Osoba do kontaktu / Contact person	
1.033 Imię i nazwisko / Full name KARIN FRICKE	1.034 Telefon / Phone
1.035 E-mail EC_REP@EDWARDS.COM	1.036 Faks / Fax

E. Identyfikacja ... / Identification of the ...1.037 I - ... Importera / ... importer
 D - ... dystrybutora / ... distributor

1.038 Numer referencyjny / Reference number	1.039 Kod kraju / Country code PL
1.040 Nazwa importera lub dystrybutora, pełna / Name of the importer or distributor, in full EDWARDS LIFESCIENCES POLAND SP. Z O.O.	
1.041 Nazwa importera lub dystrybutora, skrócona / Name of the importer or distributor, abbreviated	
1.042 Miasto / City WARSAWA	1.043 Kod pocztowy / Postal code 00-807
1.044 Ulica, nr / Street, no. ALEJE JERUZOLIMSKIE 94	1.045 Skrytka pocztowa / PO Box
Osoba do kontaktu / Contact person	
1.046 Imię i nazwisko / Full name Barbara Szostyk	1.047 Telefon / Phone 22 256 38 80
1.048 E-mail barbara_szostyk@edwards.com	1.049 Faks / Fax 22 256 38 88

F. Identyfikacja ... / Identification of the organization ...	
<input type="checkbox"/> Z - ... podmiotu zestawiającego system lub zestaw zabiegowy / ... assembling system or procedure pack <input type="checkbox"/> S - ... podmiotu sterylizującego wyrób medyczny, system lub zestaw zabiegowy / ... sterilizing medical device, system or procedure pack <input type="checkbox"/> O - ... Świadczeniodawcy wykonującego ocenę działania / ... carrying out performance evaluation <input type="checkbox"/> L - ... laboratorium wytwarzające na swój użytek wyrób IVD / Laboratory produced in home IVD device	
1.050	
1.051 Numer referencyjny / Reference number	1.052 Kod kraju / Country code
1.053 Nazwa podmiotu, pełna / Name of the organization, in full	
1.054 Nazwa podmiotu, skrócona / Name of the organization, abbreviated	
1.055 Miasto / City	1.056 Kod pocztowy / Postal code
1.057 Ulica, nr / Street, no.	1.058 Skrytka pocztowa / PO Box
Osoba do kontaktu / Contact person	
1.059 Imię i nazwisko / Full name	1.060 Telefon / Phone
1.061 E-mail	1.062 Faks / Fax

G. Identyfikacja pełnomocnika działającego w imieniu podmiotu dokonującego zgłoszenia lub powiadomienia Identification of the person acting as proxy for the organization making this notification	
Wypełnia pełnomocnik ustanowiony na mocy art. 33 KPA To be filled in by person acting as proxy in accordance with art. 33 of the Polish Code of Administrative Procedure	
1.063 Imię i nazwisko / Full name BARBARA SZOSTYK	
1.064 Miasto / City WARSZAWA	1.065 Kod pocztowy / Postal code 00-807
1.066 Ulica, nr / Street, no. ALEJE JEROZOLIMSKIE 94	1.067 Skrytka pocztowa / PO Box
1.068 Telefon / Phone	1.069 Faks / Fax

H. Liczba wyrobów objętych tym zgłoszeniem lub powiadomieniem / Number of devices covered by this notification	
Proszę podać właściwe liczby lub zero, jeśli nie dołączono danego typu formularza Please provide proper numbers or zero if there are no attached forms of given type	
1.070 Liczba dołączonych Załączników nr 2 / Number of attached forms no. 2	0
1.071 Liczba dołączonych Załączników nr 3 / Number of attached forms no. 3	0
1.072 Liczba wyrobów wymienionych w dołączonych Załącznikach nr 4 / Number of devices listed in attached forms no. 4	1

Potwierdzam, że powyższe informacje są poprawne według mojej najlepszej wiedzy.
I affirm that the information given above is correct to the best of my knowledge.

Miasto / City WARSZAWA

Data / Date 2019-05-21

Nazwisko / Name BARBARA SZOSTYK

Podpis / Signature Barbara Szostyk
Pełnomocnik

Edwards Lifesciences-Roland Sp. z o.o.
Specjalista ds. zamówień publicznych

Formularz dla podmiotów / Form for organizations

A. Identyfikacja właściwego organu / Identification of the Competent Authority	
1.001 Kod / Code PL/CA01	
1.002 Nazwa w języku miejscowym - po polsku / Name in local language - in Polish Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych	
1.003 Nazwa po angielsku / Name in English The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products	
1.004 Kod kraju / Country code PL	1.005 Kod pocztowy i miasto / Postal code and city
1.006 Ulica, nr / Street, no.	1.007 Telefon / Phone +48 22 4921100

Proszę wypełniać tylko pola z białym tłem / Please fill in fields with a white background only

B. Identyfikacja zgłoszenia lub powiadomienia / Identification of notification	
1.008 Data wpływu / Date of notification	1.009 Numer referencyjny / Reference number
1.010 Rodzaj zgłoszenia lub powiadomienia / Notification type	
<input checked="" type="checkbox"/> 1. Pierwsze dla wyrobu / First for device <input type="checkbox"/> 2. Zmiana danych podmiotu / Change of entity details <input type="checkbox"/> 3. Zmiana danych wyrobu / Change of device details	
1.011 W przypadku zmiany dotyczącej podmiotu proszę wskazać dane ulegające zmianie In case of change of entity details please indicate the data being changed	
1.012 Status podmiotu dokonującego niniejszego zgłoszenia lub powiadomienia / Status of the organization making this notification	
<input type="checkbox"/> W - Wytwórca / Manufacturer <input type="checkbox"/> A - Autoryzowany przedstawiciel / Authorized representative <input type="checkbox"/> I - Importer / Importer <input checked="" type="checkbox"/> D - Dystrybutor / Distributor <input type="checkbox"/> Z - Podmiot zestawiający system lub zestaw zabiegowy / Organization assembling system or procedure pack <input type="checkbox"/> S - Podmiot sterylizujący wyrób medyczny, system lub zestaw zabiegowy / Organization sterilizing medical device, system or procedure pack <input type="checkbox"/> O - Świadczeniodawca wykonujący ocenę działania / Organization carrying out performance evaluation <input type="checkbox"/> L - Laboratorium wytwarzające na swój użytek wyrób IVD / Laboratory produced in home IVD device	

ID: 9017 1826 0141

WM1_F1_1.4

Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych Kancelaria Główna
2018 - 11 - 21
Nr Data zgłoszenia Podpis przyjmującego

Strona Page 1 / 3

C. Identyfikacja wytwórcy / Identification of the manufacturer	
1.013 Numer referencyjny / Reference number	1.014 Kod kraju / Country code US
1.015 Nazwa wytwórcy, pełna / Name of the manufacturer, in full EDWARDS LIFESCIENCES, LLC	
1.016 Nazwa wytwórcy, skrócona / Name of the manufacturer, abbreviated	
1.017 Miasto / City IRVINE	1.018 Kod pocztowy / Postal code 92614
1.019 Ulica, nr / Street, no. ONE EDWARDS WAY	1.020 Skrytka pocztowa / PO Box
Osoba do kontaktu / Contact person	
1.021 Imię i nazwisko / Full name MOMCHIL BLAGOEV	1.022 Telefon / Phone
1.023 E-mail MOMCHIL_BLAGOEV@EDWARDS.COM	1.024 Faks / Fax
D. Identyfikacja autoryzowanego przedstawiciela / Identification of the authorized representative	
1.025 Numer referencyjny / Reference number	1.026 Kod kraju / Country code DE
1.027 Nazwa autoryzowanego przedstawiciela, pełna / Name of the authorized representative, in full EDWARDS LIFESCIENCES SERVICES GMBH	
1.028 Nazwa autoryzowanego przedstawiciela, skrócona / Name of the authorized representative, abbreviated	
1.029 Miasto / City UNTERSCHLEISSHEIM	1.030 Kod pocztowy / Postal code 85716
1.031 Ulica, nr / Street, no. EDISONSTRASSE 6	1.032 Skrytka pocztowa / PO Box
Osoba do kontaktu / Contact person	
1.033 Imię i nazwisko / Full name KARIN FRICKE	1.034 Telefon / Phone
1.035 E-mail EC_REP@EDWARDS.COM	1.036 Faks / Fax
E. Identyfikacja ... / Identification of the ...	
1.037	<input type="checkbox"/> I - ... importera / ... importer <input checked="" type="checkbox"/> D - ... dystrybutora / ... distributor
1.038 Numer referencyjny / Reference number	1.039 Kod kraju / Country code PL
1.040 Nazwa importera lub dystrybutora, pełna / Name of the importer or distributor, in full EDWARDS LIFESCIENCES POLAND SP. Z O.O.	
1.041 Nazwa importera lub dystrybutora, skrócona / Name of the importer or distributor, abbreviated	
1.042 Miasto / City WARSZAWA	1.043 Kod pocztowy / Postal code 00-807
1.044 Ulica, nr / Street, no. ALEJE JEROZOLIMSKIE 94	1.045 Skrytka pocztowa / PO Box
Osoba do kontaktu / Contact person	
1.046 Imię i nazwisko / Full name Barbara Szostyk	1.047 Telefon / Phone 22 256 38 80
1.048 E-mail barbara_szostyk@edwards.com	1.049 Faks / Fax 22 256 38 88


F. Identyfikacja ... / Identification of the organization ...	
<input type="checkbox"/> Z - ... podmiotu zestawiającego system lub zestaw zabiegowy / ... assembling system or procedure pack <input type="checkbox"/> S - ... podmiotu sterylizującego wyrób medyczny, system lub zestaw zabiegowy / ... sterilizing medical device, system or procedure pack 1.050 <input type="checkbox"/> O - ... Świadczeniodawcy wykonującego ocenę działania / ... carrying out performance evaluation <input type="checkbox"/> L - ... laboratorium wytwarzające na swój użytek wyrób IVD / Laboratory produced in-house IVD device	
1.051 Numer referencyjny / Reference number	1.052 Kod kraju / Country code
1.053 Nazwa podmiotu, pełna / Name of the organization, in full	
1.054 Nazwa podmiotu, skrócona / Name of the organization, abbreviated	
1.055 Miasto / City	1.056 Kod pocztowy / Postal code
1.057 Ulica, nr / Street, no.	1.058 Skrytka pocztowa / PO Box
Osoba do kontaktu / Contact person	
1.059 Imię i nazwisko / Full name	1.060 Telefon / Phone
1.061 E-mail	1.062 Faks / Fax
G. Identyfikacja pełnomocnika działającego w imieniu podmiotu dokonującego zgłoszenia lub powiadomienia Identification of the person acting as proxy for the organization making this notification	
Wypełnia pełnomocnik ustanowiony na mocy art. 33 KPA To be filled in by person acting as proxy in accordance with art. 33 of the Polish Code of Administrative Procedure	
1.063 Imię i nazwisko / Full name BARBARA SZOSTYK	
1.064 Miasto / City WARSZAWA	1.065 Kod pocztowy / Postal code 00-807
1.066 Ulica, nr / Street, no. ALEJE JEROZOLIMSKIE 94	1.067 Skrytka pocztowa / PO Box
1.068 Telefon / Phone	1.069 Faks / Fax
H. Liczba wyrobów objętych tym zgłoszeniem lub powiadomieniem / Number of devices covered by this notification	
Proszę podać właściwe liczby lub zero, jeśli nie dołączono danego typu formularza Please provide proper numbers or zero if there are no attached forms of given type	
1.070 Liczba dołączonych Załączników nr 2 / Number of attached forms no. 2	0
1.071 Liczba dołączonych Załączników nr 3 / Number of attached forms no. 3	0
1.072 Liczba wyrobów wymienionych w dołączonych Załącznikach nr 4 / Number of devices listed in attached forms no. 4	1

Potwierdzam, że powyższe informacje są poprawne według mojej najlepszej wiedzy.
I affirm that the information given above is correct to the best of my knowledge.

Miasto / City WARSZAWA

Nazwisko / Name BARBARA SZOSTYK

Data / Date 2018-11-19

Podpis / Signature 
Barbara Szostyk
 Pełnomocnik

Wykaz wyrobów objętych powiadomieniem
List of devices covered by this notification

Proszę wypełniać tylko pola z białym tłem / Please fill in fields with a white background only

A. Identyfikacja powiadomienia / Identification of notification	
4.001 Numer kolejny Załącznika nr 4 w obrębie tego powiadomienia 1 Ordinal number of form no. 4 within this notification	4.002 Numer referencyjny Załącznika nr 1 / Reference number of form no. 1
B. Wykaz wyrobów / List of devices	
4.003 Nr referencyjny / Ref. no	4.004 Nazwa handlowa wyrobu / Trade name of device 1), 2)
	TruWave 3 cc/60 in (150 cm), REF: PX260
	TruWave 3 cc/72 in (180 cm), REF: PX272
	TruWave 3 cc/84 in (210 cm), REF: PX284

Potwierdzam, że powyższe informacje są poprawne według mojej najlepszej wiedzy.
I affirm that the information given above is correct to the best of my knowledge.

Miasto / City Warszawa

Data / Date 2019-05-21

Nazwisko / Name Barbara Szostyk

Edwards Lifesciences Poland Sp. z o.o.
Specjalista ds. zamówień publicznych
Podpis / Signature

Barbara Szostyk
Pełnomocnik

- 1) Wyroby różniące się nazwą handlową, typem, modelem, wersją wykonania, wersją oprogramowania, rozmiarem, kształtem lub wymiarami można uznać za jeden wyrób i zamieścić w jednym powiadomieniu, jeżeli są lub mają:
- jednego wytwórcę,
 - jednego autoryzowanego przedstawiciela, jeżeli ich wytwórca nie ma siedziby lub miejsca zamieszkania w państwie członkowskim,
 - jeden, wspólny, krótki opis wyrobu i jego przewidziane zastosowanie,
 - jedną, możliwie najbardziej szczegółową nazwę rodzajową,
 - jeden kod wyrobu według Globalnej Nomenklatury Wyrobów Medycznych albo Innej uznanej nomenklatury wyrobów medycznych,
 - tę samą klasyfikację albo kwalifikację,
 - wspólną ocenę zgodności wykonaną z użyciem tych samych procedur oceny zgodności,
 - wspólny certyfikat zgodności lub wspólne certyfikaty zgodności, jeżeli w ocenie ich zgodności brała udział jednostka notyfikowana,
 - jeden numer referencyjny w bazie EUDAMED i jedną nazwę handlową w języku polskim albo jedną nazwę handlową w języku angielskim.
- 2) Systemy lub zestawy zabiegowe o tym samym przeznaczeniu, zestawione przez ten sam podmiot i zawierające te same wyroby medyczne, które w poszczególnych systemach lub zestawach zabiegowych występują w różnych ilościach lub różnią się nazwą handlową, typem, modelem, wersją wykonania, wersją oprogramowania, rozmiarem, kształtem lub wymiarami można uznać za jeden system lub zestaw zabiegowy, jeżeli odpowiadające sobie wyroby medyczne w poszczególnych systemach lub zestawach zabiegowych mogą być uznane za jeden wyrób zgodnie z pkt 1.

Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych Kancelaria Główna	
2019-05-24	
Nr
Ilość załączników-9-
Podpis przysyłającego	Strona / Page 1 / 1

Wykaz wyrobów objętych powiadomieniem

List of devices covered by this notification

Proszę wypełniać tylko pola z białym tłem / Please fill in fields with a white background only

A. Identyfikacja powiadomienia / Identification of notification	
4.001 Numer kolejny Załącznika nr 4 w obrębie tego powiadomienia 13 Ordinal number of form no. 4 within this notification	4.002 Numer referencyjny Załącznika nr 1 / Reference number of form no. 1
B. Wykaz wyrobów / List of devices	
4.003 Nr referencyjny / Ref. no	4.004 Nazwa handlowa wyrobu / Trade name of device 1), 2)
	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer) (Model: Załącznik nr 1)
	LASS Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer) (Model: T005025M)
	FloTrac Sensor (Model: MHD6xxx/MHD8xxx)

Potwierdzam, że powyższe informacje są poprawne według mojej najlepszej wiedzy.
 I affirm that the information given above is correct to the best of my knowledge.

Miasto / City Warszawa **Data / Date** 2015-06-15

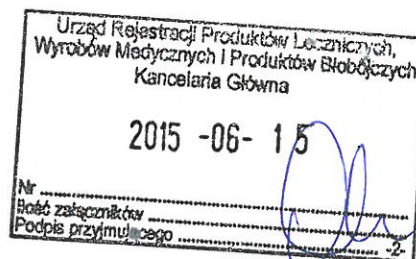
Nazwisko / Name Małgorzata Dobrogosz

Podpis / Signature

EDWARDS LIFESCIENCES POLAND SP. Z O.O.
 Office Supervisor

Małgorzata Dobrogosz

- 1) Wyroby różniące się nazwą handlową, typem, modelem, wersją wykonania, wersją oprogramowania, rozmiarem, kształtem lub wymiarami można uznać za jeden wyrób i zamieścić w jednym powiadomieniu, jeżeli są lub mają:
- jednego wytwórcę,
 - jednego autoryzowanego przedstawiciela, jeżeli ich wytwórca nie ma siedziby lub miejsca zamieszkania w państwie członkowskim,
 - jeden, wspólny, krótki opis wyrobu i jego przewidziane zastosowanie,
 - jedną, możliwie najbardziej szczegółową nazwę rodzajową,
 - jeden kod wyrobu według Globalnej Nomenklatury Wyrobów Medycznych albo innej uznanej nomenklatury wyrobów medycznych,
 - tę samą klasyfikację albo kwalifikację,
 - wspólną ocenę zgodności wykonaną z użyciem tych samych procedur oceny zgodności,
 - wspólny certyfikat zgodności lub wspólne certyfikaty zgodności, jeżeli w ocenie ich zgodności brała udział jednostka notyfikowana,
 - jeden numer referencyjny w bazie EUDAMED i jedną nazwę handlową w języku polskim albo jedną nazwę handlową w języku angielskim.
- 2) Systemy lub zestawy zabiegowe o tym samym przeznaczeniu, zestawione przez ten sam podmiot i zawierające te same wyroby medyczne, które w poszczególnych systemach lub zestawach zabiegowych występują w różnych ilościach lub różnią się nazwą handlową, typem, modelem, wersją wykonania, wersją oprogramowania, rozmiarem, kształtem lub wymiarami można uznać za jeden system lub zestaw zabiegowy, jeżeli odpowiadające sobie wyroby medyczne w poszczególnych systemach lub zestawach zabiegowych mogą być uznane za jeden wyrób zgodnie z pkt 1.



Załącznik nr 1 do Form.4 ID: 0003 1339 8031

ID_FORM_000 3 1339 8031	Code No.
Pozycja nr 1	T001619A
Pozycja nr 1	T001624A
Pozycja nr 1	T001631A
Pozycja nr 1	T001633A
Pozycja nr 1	T001645A
Pozycja nr 1	T001650A
Pozycja nr 1	T001657A
Pozycja nr 1	T001658A
Pozycja nr 1	T001660A
Pozycja nr 1	T001702A
Pozycja nr 1	T001709A
Pozycja nr 1	T001712A
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