angiodynamics

also D.B.A Navilyst Medical, Inc

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Navilyst Medical, Inc. 26 Forest Street Marlborough, MA 01752 USA
Manufacturing Site(s):	AngioDynamics, Inc. 603 Queensbury Avenue Queensbury, New York 12804 USA
EU Authorized Representative:	Donawa Lifescience Consulting Srl Piazza Albania, 10 00153 Rome Italy
Product:	**Chronic Dialysis Catheters** Design Dossier P001683 See Attachment-Product List
GMDN:	37278, Double-lumen haemodialysis catheter, Implantable
Classification:	Class III, Rule 8 according to Annex IX of the MDD
CE Certificate:	CE 622285, Dated: 2021-04-28
DE Certificate(s):	CE 623831 – BioFlo DuraMax with Endexo Technology Hemodialysis Catheter and Accessories, Dated: 2020-10-15

We declare that the product identified above is in conformity with all relevant provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices. This declaration is made under Annex II of this directive. All supporting information is retained under the control of the Legal Manufacturer.

Notified Body:	BSI Say Building, John M. Keynesplein 9 1066 EP Amsterdam The Netherlands Identification Number: 2797

Signature, Date of Issue:

Name: Troy Roberts
Title: Vice President, Regulatory Affairs

Signature: _____ **Date:** November 17, 2021

Attachment – Product List

BIOFLO DURAMAX WITH ENDEXO TECHNOLOGY CHRONIC HEMODIALYSIS CATHETER		
Material/UPN:	Ref:	Description:
H965103028011	02-801	20cm/Basic Kit/Dual Valve
H965103028021	02-802	22cm/Basic Kit/Dual Valve
H965103028031	02-803	24cm/Basic Kit/Dual Valve
H965103028041	02-804	28cm/Basic Kit/Dual Valve
H965103028051	02-805	32cm/Basic Kit/Dual Valve
H965103028061	02-806	36cm/Basic Kit/Dual Valve
H965103028070	02-807	40cm/Basic Kit/Dual Valve
H965103028080	02-808	48cm/Basic Kit/Dual Valve
H965103028090	02-809	55cm/Basic Kit/Dual Valve
H965103028161	02-816	20cm/VascPak/Dual Valve
H965103028171	02-817	22cm/VascPak/Dual Valve
H965103028181	02-818	24cm/VascPak/Dual Valve
H965103028191	02-819	28cm/VascPak/Dual Valve
H965103028201	02-820	32cm/VascPak/Dual Valve
H965103028211	02-821	36cm/VascPak/Dual Valve
H965103028220	02-822	40cm/VascPak/Dual Valve
H965103028230	02-823	48cm/VascPak/Dual Valve
H965103028240	02-824	55cm/VascPak/Dual Valve
H965103029011	02-901	20cm/Catheter Kit
H965103029021	02-902	22cm/Catheter Kit
H965103029031	02-903	24cm/Catheter Kit
H965103029041	02-904	28cm/Catheter Kit
H965103029051	02-905	32cm/Catheter Kit
H965103029061	02-906	36cm/Catheter Kit
H965103029071	02-907	40cm/Catheter Kit
H965103029081	02-908	48cm/Catheter Kit
H965103029091	02-909	55cm/Catheter Kit
H965103038011	03-801	20cm/Basic Kit/Single Valve
H965103038021	03-802	22cm/Basic Kit/Single Valve
H965103038031	03-803	24cm/Basic Kit/Single Valve
H965103038041	03-804	28cm/Basic Kit/Single Valve
H965103038051	03-805	32cm/Basic Kit/Single Valve
H965103038061	03-806	36cm/Basic Kit/Single Valve
H965103038070	03-807	40cm/Basic Kit/Single Valve
H965103038080	03-808	48cm/Basic Kit/Single Valve
H965103038090	03-809	55cm/Basic Kit/Single Valve
H965103038161	03-816	20cm/VascPak Kit/Single Valve
H965103038171	03-817	22cm/VascPak Kit/Single Valve
H965103038181	03-818	24cm/VascPak Kit/Single Valve
H965103038191	03-819	28cm/VascPak/Single Valve
H965103038201	03-820	32cm/VascPak/Single Valve
H965103038211	03-821	36cm/VascPak/Single Valve
H965103038220	03-822	40cm/VascPak/Single Valve
H965103038230	03-823	48cm/VascPak/Single Valve
H965103038240	03-824	55cm/VascPak/Single Valve

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także D.B.A Navilyst Medical, Inc

DEKLARACJA ZGONOŚCI CE

Legalny producent:	Navilyst Medical, Inc. 26 Forest Street Marlborough, MA 01752 USA
Miejsce produkcji:	AngioDynamics, Inc. 603 Queensbury Avenue Queensbury, New York 12804 USA
Autoryzowany przedstawiciel UE:	Donawa Lifescience Consulting Srl Piazza Albania, 10 00153 Rome Italy
Produkt:	Cewniki do przewlekłej dializy Dokumentacja projektowa P001683 Patrz załacznik – lista produktów
GMDN:	37278, cewnik do hemodializy o podwójnym świetle, wszczepialny
Klasyfikacja:	Klasa III, Reguła 8 zgodnie z aneksem IX dyrektywy MDD
Ceryfikat CE	CE 622285, Datowany: 2021-04-28
Certyfikat DE	CE 623831 - BioFlo DuraMax z cewnikiem do hemodializy Endexo Technology i akcesoriami, Datowany: 2020-10-15

Oświadczamy, że wskazany powyżej produkt jest zgodny ze wszystkimi obowiązującymi postanowieniami Dyrektywy Rady 93/42/EEC z dnia 14 czerwca 1993 dotyczącej wyrobów medycznych. Niniejsza deklaracja jest sporządzona zgodnie z załącznikiem II do niniejszej dyrektywy. Wszystkie informacje uzupełniające są przechowywane pod kontrolą legalnego producenta.

Jednostka Notyfikowana

BSI
Say Building, John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands
Numer Jednostki: 2797

Podpis, Data wydania

Nazwisko: Troy Roberts

Tytuł: Wiceprezes ds. Regulacyjnych

Podpis: *podpis nieczytelny* *Data : 17 Październik 2021*

Załącznik – Lista produktów

BIOFLO DURAMAX WITH ENDEXO TECHNOLOGY Cewniki do przewlekłej dializy		
Material/UPN:	Ref:	Opis
H965103028011	02-801	20cm/Basic Kit/Dual Valve
H965103028021	02-802	22cm/Basic Kit/Dual Valve
H965103028031	02-803	24cm/Basic Kit/Dual Valve
H965103028041	02-804	28cm/Basic Kit/Dual Valve
H965103028051	02-805	32cm/Basic Kit/Dual Valve
H965103028061	02-806	36cm/Basic Kit/Dual Valve
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H965103028211	02-821	36cm/VascPak/Dual Valve
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H965103028230	02-823	48cm/VascPak/Dual Valve
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H965103038171	03-817	22cm/VascPak Kit/Single Valve
H965103038181	03-818	24cm/VascPak Kit/Single Valve
H965103038191	03-819	28cm/VascPak/Single Valve
H965103038201	03-820	32cm/VascPak/Single Valve
H965103038211	03-821	36cm/VascPak/Single Valve
H965103038220	03-822	40cm/VascPak/Single Valve
H965103038230	03-823	48cm/VascPak/Single Valve
H965103038240	03-824	55cm/VascPak/Single Valve