



DECLARATION OF CONFORMITY

Application of Council Directive(s):

Council Directive 93/42/EEC (as amended 2007/47/EC)

Conformity Assessment Route:

Annex II, excluding Section 4, of Council Directive 93/42/EEC

Standards to which Conformity is Declared:

EN 1041: 2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 15223-1: 2016	Medical devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 11137-1:2021	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
EN ISO 11137-2: 2015	Sterilization of health care products - Radiation -Part 2: Establishing the sterilization dose
EN 556-1: 2001	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
ISO 11607-1:2020	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971: 2019	Medical devices - Application of risk management to medical devices
EN ISO 10993-10:2021	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Manufacturer's Name and Address:

KORU Medical Systems
100 Corporate Drive
Mahwah, New Jersey
07430
United States of America

Sterilization Address:

Steris Isomedix Services



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**Authorised European
Representative:**

ICON (LR) Limited
South County Business Park
Leopardstown, Dublin D18 X5R3
Ireland

Notified Body:

British Standards Institution (BSI)
Phone: +31 20 346 0780
Notified Body number: 2797

Type of Device:

The Freedom Infusion System Tubing and Needle Sets

**Device classification per MDD
93/42/EEC:**

Class IIa per Rule 7

GMDN Code:

Mechanical infusion pump administration set [46846]

Model Numbers:

Precision Flow Rate Tubing™	
SKU	PRODUCT DESCRIPTION
F120	120 IV FLOW TUBING SET
F15	15 IV FLOW TUBING SET
F30	30 IV FLOW TUBING SET
F45	45 IV FLOW TUBING SET
F60	60 IV FLOW TUBING SET
F0.5	0.5 IV FLOW TUBING SET
F1	1 IV FLOW TUBING SET
F10	10 IV FLOW TUBING SET
F1200	1200 IV FLOW TUBING SET
F180	180 IV FLOW TUBING SET
F2	2 IV FLOW TUBING SET
F2400	2400 IV FLOW TUBING SET
F275	275 IV FLOW TUBING SET



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F8	8 IV FLOW TUBING SET
F900	900 IV FLOW TUBING SET
LRVY	LOW RESIDUAL VOLUME Y CONNECTOR
FEXT	HIGH FLOW NEEDLE EXTENSION SET

Precision Flow Rate Tubing™ Kits

SKU	PRODUCT DESCRIPTION
L20KT	(3) F30, (2) F45, (8) F60, (4) F120, (3) F180
H20KT	(2) F275, (5) F600, (5) F900, (4) F1200, (4) F2400

HigH-Flo™ Subcutaneous Safety Needle Sets

SKU	PRODUCT DESCRIPTION
RMS12406	24" 1 NEEDLE 24G 6mm
RMS12409	24" 1 NEEDLE 24G 9mm
RMS12412	24" 1 NEEDLE 24G 12mm
RMS12414	24" 1 NEEDLE 24G 14mm
RMS22406	24" 2 NEEDLE 24G 6mm
RMS22409	24" 2 NEEDLE 24G 9mm
RMS22412	24" 2 NEEDLE 24G 12mm
RMS22414	24" 2 NEEDLE 24G 14mm
RMS32406	24" 3 NEEDLE 24G 06mm
RMS32409	24" 3 NEEDLE 24G 09mm
RMS32412	24" 3 NEEDLE 24G 12mm
RMS32414	24" 3 NEEDLE 24G 14mm
RMS42406	24" 4 NEEDLE 24G 6mm
RMS42409	24" 4 NEEDLE 24G 9mm
RMS42412	24" 4 NEEDLE 24G 12mm
VHF	VERY HIGH FLOW TUBING SET
RMS12604	20" 1 NEEDLE 26G 4mm

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RMS22604	20" 2 NEEDLE 26G 4mm
RMS22606	20" 2 NEEDLE 26G 6mm
RMS22609	20" 2 NEEDLE 26G 9mm
RMS22612	20" 2 NEEDLE 26G 12mm
RMS22614	20" 2 NEEDLE 26G 14mm
RMS32604	20" 3 NEEDLE 26G 4mm
RMS32606	20" 3 NEEDLE 26G 6mm
RMS32609	20" 3 NEEDLE 26G 9mm
RMS32612	20" 3 NEEDLE 26G 12mm
RMS32614	20" 3 NEEDLE 26G 14mm
RMS42604	20" 4 NEEDLE 26G 4mm
RMS42606	20" 4 NEEDLE 26G 6mm
RMS42609	20" 4 NEEDLE 26G 9mm
RMS42612	20" 4 NEEDLE 26G 12mm
RMS42614	20" 4 NEEDLE 26G 14mm
RMS52604	20" 5 NEEDLE 26G 4mm
RMS52606	20" 5 NEEDLE 26G 6mm
RMS52609	20" 5 NEEDLE 26G 9mm
RMS52612	20" 5 NEEDLE 26G 12mm
RMS52614	20" 5 NEEDLE 26G 14mm
RMS62604	20" 6 NEEDLE 26G 4mm
RMS62606	20" 6 NEEDLE 26G 6mm
RMS62609	20" 6 NEEDLE 26G 9mm
RMS62612	20" 6 NEEDLE 26G 12mm
RMS62614	20" 6 NEEDLE 26G 14mm

We, the manufacturer, hereby declare that the medical device (s) specified above conforms to the applicable standards identified above and the provisions of EC Directive 93/142/EEC as amended by 2007/147/EC Annex II.



20-Jan-2023