



TITLE: EU MDR Declaration of Conformity
 – TECHDOC-1 – Infusion Pumps
DOCUMENT NO.: MDR-DOC-1
REVISION: C
DATE: 23-Dec-2025

This Declaration of Conformity is issued under the sole responsibility of Koru Medical Systems, Inc. The device covered by the present Declaration is in conformity with the EU MDR 2017/745 below, including compliance with related General Safety and Performance Requirements.

1. Object of the Declaration:

Product Name	Freedom Infusion System – Infusion Pumps		
Trade Name	Freedom Infusion System – Infusion Pumps		
Product Type	Mechanical reusable syringe driver		
Intended Purpose	The Freedom Infusion Pumps are intended to subcutaneously administer prescribed medicinal products to the body for therapeutic purposes.		
Product Part Number and Descriptions	Device(s)	Product/Trade Name	GTIN (UDI-DI)
	F10050	Freedom60 Infusion Pump	00659443000001
	F10050-B	Freedom60 Infusion Pump – Language Configuration B	00659443004474
	F10050-C	Freedom60 Infusion Pump– Language Configuration C	00659443004481
	F10050-D	Freedom60 Infusion Pump – Language Configuration D	00659443004498
	F10050-E	Freedom60 Infusion Pump – Language Configuration E	00659443004504
	348143	Freedom60 Prefilled Syringe Adapter	00659443003118
	348145	Freedom60 Prefilled Syringe Adapter – Box of 10	00659443003132
	F10020	FreedomEdge Infusion Pump	00659443000018
	F10020-B	FreedomEdge Infusion Pump – Language Configuration B	00659443001770
	F10020-C	FreedomEdge Infusion Pump– Language Configuration C	00659443002289
	F10020-D	FreedomEdge Infusion Pump – Language Configuration D	00659443002777
	F10020-E	FreedomEdge Infusion Pump – Language Configuration E	00659443004467
	Basic UDI-DI	065944301PE – FreedomEdge Infusion Pump 065944302PG – Freedom60 Infusion Pump and Adapter	
European Medical Device Nomenclature Code (EMDN) Code	A99		
European Medical Device Nomenclature Code (EMDN) Code Description	DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION - OTHER		

The object of the Declaration described above is in conformity with the following regulations:

EU Directive	EU MDR 2017/745
Device Risk Classification	Class IIa
Conformity Assessment Path	Annex IX Chapters I and III



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Standards	The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below. Details regarding compliance are specified in the technical documentation for the devices.	
	Standard Number:	Description:
	AAMI TIR12:2020	Designing, Testing, And Labeling Medical Devices Intended For Processing By Health Care Facilities: A Guide For Device Manufacturers
	AAMI TIR30:2011(R) 2016)	A Compendium Of Processes, Materials, Test Methods, And Acceptance Criteria For Cleaning Reusable Medical Devices
	ASTM D4169-22	Standard Practice For Performance Testing Of Shipping Containers And Systems
	EN ISO 10993-5:2017	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
	EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	ISO 28620:2020	Medical devices — Non-electrically driven portable infusion devices
	IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical
	EN ISO 13485:2016/ AC:2018, A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
	ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good clinical practice
	ISO 14971:2019, A11:2021	Medical devices - Application of risk management to medical devices
	ISO 20417:2021	Information to be supplied by the manufacturer of a medical device
ISTA 3A:2018	Packaged Products for Parcel Delivery System Shipment - 70 kg (150 lb) or Less	

2. Manufacturer Information:

Manufacturer Name	Koru Medical Systems, Inc
Manufacturer Address	100 Corporate Drive Mahwah, New Jersey USA 07430
Single Registration Number (SRN)	US-MF-000025369
EU Authorized Representative Information	ICON (LR) Limited South County Business Park, Leopardstown, Dublin 18 D18 X5R3, Ireland



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EU and UK Authorized Representative SRN	IE-AR-000006507
Swiss Authorized Representative	MedEnvoy Switzerland
Swiss Authorized Representative SRN	CHRN-AR-20000310

Notified Body Information:

Notified Body Name	BSI Netherlands
Notified Body Address	Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands
Notified Body Number	2797
CE Certificate Number	MDR 784460

Signature (signed for and on behalf of Koru Medical Systems)

23-Dec-2025

Date of Issue:

Printed Name: Christine Trefethen

Title: Senior Director of Quality and Regulatory Affairs

Place of Issue: Mahwah, NJ