

EC Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of Belmont Medical Technologies.

MANUFACTURER		
Name of Company	Address	SRN
Belmont Medical Technologies	780 Boston Road, Billerica, MA 01821, US	US-MF-000007062

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Phone/email
Emergo Europe	Westervoortsedijk 60, 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product Name	Code / Catalog Number
Hyperthermia Pump™ and Disposables	See Table-1 for list of Codes/Catalog Number
Intended Purpose	Basic UDI-DI
The Hyperthermia Pump™ is designed to raise the temperature of the thoracic or peritoneal cavity to the desired target temperature by continuously lavaging the cavity with circulating warmed sterile solution, according to a protocol to be selected by the physician.	08961280020000028F (Hyperthermia Pump™) 08961280020000078R (Disposable) 08961280020000068P (Disposable)

RISK CLASS FOR DEVICES		
Device Classification		Common Specifications
Class:	IIa and IIb	SEE Table-2 FOR LIST OF COMMON SPECIFICATIONS
Rule:	Rule 2, 9 and 11	

NOTIFIED BODY			
Name of Company	ID Number	Conformity Assessment Procedure	Certificate Reference(s)/ Expiration date
Polish Centre for Testing and Certification, PCBC 469 Pulawska Street, 02-844 Warsaw, POLAND	1434	COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC) Annex II excluding section 4	1434-MDD-374/2021 Class IIa (26 May 2024) And 1434-MDD-483/2019 Class IIb (8 July 2024)

Belmont Medical Technologies declares that the above-mentioned products meet the provision of the following EU legislation:

- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC) Annex II excluding section 4.
- EU 2023/607 Transitional provisions for certain medical devices and in vitro diagnostic medical devices
- RoHS Directive EU 2015/863.

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COMPANY REPRESENTATIVE:
TITLE: Director Quality Assurance and Regulatory Affairs

PLACE: Billerica, MA, USA

SIGNATURE: Lida Reed


DATE: 07 May 2024

Table 1: Product names and Codes

Product Name	GMDN Code
902-00001 Hyperthermia Pump™ 120V	Extravascular-circulation Hyperthermia System, 40784
902-00001A Hyperthermia Pump™ 230V	Extravascular-circulation Hyperthermia System, 40784
902-00006 Hyperthermic Lavage Heat Exchanger Set	Extravascular-circulation hyperthermia system applicator, intracorporeal 40796
902-00034 4.4 Liter Reservoir, Hyperthermia	Extravascular-circulation hyperthermia system applicator, intracorporeal 40796
902-00036 Cannula Connector, Hyperthermia Pump™ Disposable	Extravascular-circulation hyperthermia system applicator, intracorporeal 40796
902-00037 Straight Inflow/Outflow Patient Line Kit	Extravascular-circulation hyperthermia system applicator, intracorporeal 40796
902-00038 Straight Inflow/Bifurcated Outflow Patient Line Kit	Extravascular-circulation hyperthermia system applicator, intracorporeal 40796
902-00039 Straight Inflow/Outflow Patient Line	Extravascular-circulation hyperthermia system applicator, intracorporeal 40796
902-00040 Straight Inflow/Bifurcated Outflow Patient Line	Extravascular-circulation hyperthermia system applicator, intracorporeal 40796
902-00045 Hyperthermia Pump™ Procedure Kit	Extravascular-circulation hyperthermia system applicator, intracorporeal 40796
902-00048 Procedure Pack	Extravascular-circulation hyperthermia system applicator, intracorporeal 40796

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Table 2: Common Specification applied in full or in part.

Common Specification	Title	Version
N/A	N/A	N/A