



## **Declaration of Conformity**

**According to Annex II of the Council Directive 93/42/EEC  
and the requirements of  
RoHS Directive 2011/65/EU**

Manufacturer  
Address Belmont Medical Technologies  
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Billerica, MA 01821, USA

Authorized European  
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We, Belmont Medical Technologies, declare under our sole responsibility, that this Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

### **DIRECTIVES**

#### **General applicable directives:**

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC) and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (also known as "RoHS Recast").

<b>CE Certificate Number Class of Devices Covered</b>	<b>Notified Body Name and Address</b>	<b>Notified Body Number</b>	<b>Date of First Issue of Certificate</b>
1434-MDD-391/2019 Class IIa	Polish Centre for Testing and Certification 23A Kłobucka Street 02-699 Warsaw Poland	1434	July 09, 2019
1434-MDD-483/2019 Class IIb	Polish Centre for Testing and Certification 23A Kłobucka Street 02-699 Warsaw Poland	1434	April 26, 2019

Signature

Name

Dori Koza

Date

May 17, 2021

Position

Director, Quality Assurance & Regulatory Affairs



**This appendix declares the products included in the Declaration of Conformity**

REF	Class	MDD Rule	MDD Conformity Assessment Route	GMDN Code
903-00037 Belmont Rapid Infuser RI-2 120V 1000ml/min	IIb	Rule 11	Annex II	Infusion pump, high-flow, warming, 17907
903-00037A Belmont Rapid Infuser RI-2 230V 1000ml/min	IIb	Rule 11	Annex II	Infusion pump, high-flow, warming, 17907
903-00039 Belmont Rapid Infuser RI-2 120V 750ml/min	IIb	Rule 11	Annex II	Infusion pump, high-flow, warming, 17907
903-00039A Belmont Rapid Infuser RI-2 230V 750ml/min	IIb	Rule 11	Annex II	Infusion pump, high-flow, warming, 17907
903-00022 Patient line Extension	IIa	Rule 2	Annex II	Conduction blood/fluid warmer., 47618
903-00004 Dual Patient Line	IIa	Rule 2	Annex II	Conduction blood/fluid warmer, 47618
903-00018 3.0 Liter Reservoir	IIa	Rule 2	Annex II	Conduction blood/fluid warmer, 47618
903-00006 3-Spike Disposable Set (qty. 12)	IIb	Rule 9	Annex II	Intravenous administration set Heat-exchanging, 41609
903-00032 3.0 Liter Reservoir with Heat Exchanger Pt Line	IIb	Rule 9	Annex II	Intravenous administration set Heat-exchanging, 41609
903-00106 3-Spike Disposable Set (qty. 6)	IIb	Rule 9	Annex II	Intravenous administration set Heat-exchanging, 41609

