

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
buddy™ lite/AC and Disposables	See Table-1 for list of Codes/Catalog Number
Intended Purpose	Basic UDI-DI
The buddy™ Blood/Fluid Warmer product family is to be used for warming blood, blood products and intravenous solutions prior to administration. It is intended to be used by healthcare professionals in a clinical environment to prevent hypothermia.	08961280020000038H (buddy™ lite/AC) 08961280020000088T (Disposable)

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

SIGNATURE: Lida Reed



PLACE: Billerica, MA, USA

DATE: 12 April 2024

Table 1: Product names and Codes

Product Name	GMDN Code
905-00016 buddy™ lite, European	Conduction blood/fluid warmer, 47616
905-00016-G buddy™ lite, German	Conduction blood/fluid warmer, 47616
905-00017 buddy™ lite, North America	Conduction blood/fluid warmer, 47616
905-00018 buddy™ lite, United Kingdom	Conduction blood/fluid warmer, 47616
905-00019 buddy™ lite, Switzerland	Conduction blood/fluid warmer, 47616
905-00029 buddy™ lite, Netherlands	Conduction blood/fluid warmer, 47616
905-00038 buddy™ lite, Sweden	Conduction blood/fluid warmer, 47616
905-00045 buddy™ lite, Australia	Conduction blood/fluid warmer, 47616
905-00022 buddy™ lite AC, North America	Conduction blood/fluid warmer, 47616
905-00023 buddy™ lite AC, European	Conduction blood/fluid warmer, 47616
905-00023-G buddy™ lite AC, German	Conduction blood/fluid warmer, 47616

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905-00010 buddy™ disposable set	Conduction blood/fluid warming set, 47618
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Table 2: Common Specification applied in full or in part.

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