

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
Thermoregulation Devices (Allon®, CritiCool® and CritiCool® MINI)	See Table-1 for list of Codes/Catalog Number
Intended Purpose	Basic UDI-DI
Thermal regulating system is indicated for monitoring and controlling patient temperature.	08961280020000098V (Allon®) 08961280020000108E (CritiCool®) 08961280020000118G (CritiCool® MINI)

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

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-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: 05 September 2023

Table 1: Product names and Codes

Product Name	GMDN Code
Allon® Part number 200-00263	Circulating-fluid whole- body heating/cooling system control unit, 36956
CritiCool® Part number 200-00236	Circulating-fluid whole- body heating/cooling system control unit, 36956
CritiCool® MINI Part number 200-00336	Circulating-fluid whole- body heating/cooling system control unit, 36956

Table 2: Common Specification applied in full or in part

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