



Declaration of Conformity

**According to Annex II and III of the European Medical
Device Regulation 2017/745
and the requirements of
RoHS Directive 2015/863**

Manufacturer Address Belmont Medical Technologies
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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.

Regulations / Directives

The devices listed in this declaration are in conformity with the following:

Medical Device Regulation: REGULATION (EU) of the European Parliament and the Council of 5 April 2017 concerning medical devices (EU MDR 2017/745) and Directive 2015/863 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (also known as "RoHS 3").

Signature

A handwritten signature in blue ink that reads "Dori Koza".

Name

Dori Koza

Date

May 26, 2021

Position

Director, Quality Assurance & Regulatory Affairs



This appendix declares the products included in the Declaration of Conformity

REF	Class	MDR Rule	MDR Conformity Assessment Route	UDI	GMDN Code
500-03148 Pediatric ThermoWrap, 122-135cm (qty. 1)	I	Rule 1	Annex II and III	07290012127236	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
506-03148 Pediatric ThermoWrap, 122-135cm (qty. 6)	I	Rule 1	Annex II and III	57290012127231	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
512-03148 Pediatric ThermoWrap, 122-135cm (qty. 12)	I	Rule 1	Annex II and III	27290012127230	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
500-03153 Universal ThermoWrap, 135-152cm (qty. 1)	I	Rule 1	Annex II and III	07290012127243	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
506-03153 Universal ThermoWrap, 135-152cm (qty. 6)	I	Rule 1	Annex II and III	57290012127248	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
512-03153 Universal ThermoWrap, 135-152cm (qty. 12)	I	Rule 1	Annex II and III	27290012127247	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
500-03160 Universal ThermoWrap, 152-168cm (qty. 1)	I	Rule 1	Annex II and III	07290012127250	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
506-03160 Universal ThermoWrap, 152-168cm (qty. 6)	I	Rule 1	Annex II and III	57290012127255	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
512-03160 Universal ThermoWrap, 152-168cm (qty. 12)	I	Rule 1	Annex II and III	27290012127254	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
500-03166 Universal ThermoWrap, 168-180cm (qty. 1)	I	Rule 1	Annex II and III	07290012127267	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
506-03166 Universal ThermoWrap, 168-180cm (qty. 6)	I	Rule 1	Annex II and III	57290012127262	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
512-03166 Universal ThermoWrap, 168-180cm (qty. 12)	I	Rule 1	Annex II and III	27290012127261	61251, Circulating-fluid whole-body heating/cooling system pad, single-use

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500-03363 Cardiac ThermoWrap, 165-182cm (qty. 1)	I	Rule 1	Annex II and III	07290012127274	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
506-03363 Cardiac ThermoWrap, 165-182cm (qty. 6)	I	Rule 1	Annex II and III	57290012127279	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
512-03363 Cardiac ThermoWrap, 165-182cm (qty. 12)	I	Rule 1	Annex II and III	27290012127278	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
500-03500 Adult CureWrap, 168-180cm (qty. 1)	I	Rule 1	Annex II and III	07290012127175	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
504-03500 Adult CureWrap, 168-180cm (qty. 4)	I	Rule 1	Annex II and III	77290012127174	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
508-03500 Adult CureWrap, 168-180cm (qty. 8)	I	Rule 1	Annex II and III	17290012127172	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
500-03518 Infant CureWrap, 2.5-4Kg (qty. 1)	I	Rule 1	Annex II and III	07290012127182	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
504-03518 Infant CureWrap, 2.5-4Kg (qty. 4)	I	Rule 1	Annex II and III	77290012127181	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
508-03518 Infant CureWrap, 2.5-4Kg (qty. 8)	I	Rule 1	Annex II and III	17290012127189	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
500-03521 Infant CureWrap, 4-7Kg (qty. 1)	I	Rule 1	Annex II and III	07290012127199	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
504-03521 Infant CureWrap, 4-7Kg (qty. 4)	I	Rule 1	Annex II and III	77290012127198	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
508-03521 Infant CureWrap, 4-7Kg (qty. 8)	I	Rule 1	Annex II and III	17290012127196	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
500-03525 Infant CureWrap, 7-11Kg (qty. 1)	I	Rule 1	Annex II and III	07290012127328	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
504-03525 Infant CureWrap, 7-11Kg (qty. 4)	I	Rule 1	Annex II and III	77290012127327	61251, Circulating-fluid whole-body heating/cooling system pad, single-use

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508-03525 Infant CureWrap, 7-11Kg (qty. 8)	I	Rule 1	Annex II and III	17290012127325	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
500-03531 Pediatric CureWrap, 79-91cm (qty. 1)	I	Rule 1	Annex II and III	07290012127335	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
504-03531 Pediatric CureWrap, 79-91cm (qty. 4)	I	Rule 1	Annex II and III	77290012127334	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
508-03531 Pediatric CureWrap, 79-91cm (qty. 8)	I	Rule 1	Annex II and III	17290012127332	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
500-03536 Pediatric CureWrap, 91-104cm (qty. 1)	I	Rule 1	Annex II and III	07290012127342	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
504-03536 Pediatric CureWrap, 91-104cm (qty. 4)	I	Rule 1	Annex II and III	77290012127341	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
508-03536 Pediatric CureWrap, 91-104cm (qty. 8)	I	Rule 1	Annex II and III	17290012127349	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
500-03541 Pediatric CureWrap, 104-122cm (qty. 1)	I	Rule 1	Annex II and III	07290012127373	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
504-03541 Pediatric CureWrap, 104-122cm (qty. 4)	I	Rule 1	Annex II and III	77290012127372	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
508-03541 Pediatric CureWrap, 104-122cm (qty. 8)	I	Rule 1	Annex II and III	17290012127370	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
500-03548 Pediatric CureWrap, 122-135cm (qty. 1)	I	Rule 1	Annex II and III	07290012127380	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
504-03548 Pediatric CureWrap, 122-135cm (qty. 4)	I	Rule 1	Annex II and III	77290012127389	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
508-03548 Pediatric CureWrap, 122-135cm (qty. 8)	I	Rule 1	Annex II and III	17290012127387	61251, Circulating-fluid whole-body heating/cooling system pad, single-use

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PED-SM008 Pediatric CureWrap, Small (qty. 4 of 500-03518 and qty. 4 of 500-03521)	I	Rule 1	Annex II and III	17290107580080	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
PED-MD008 Pediatric CureWrap, Medium (qty. 4 of 500-03525 and qty. 4 of 500-03531)	I	Rule 1	Annex II and III	17290107580134	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
PED-LA008 Pediatric CureWrap, Large (qty. 4 of 500-03536 and qty. 4 of 500-03541)	I	Rule 1	Annex II and III	17290107580189	61251, Circulating-fluid whole-body heating/cooling system pad, single-use
PED-XL008 Pediatric CureWrap, X-Large (qty. 4 of 500-03548 and qty. 4 of 500-03500)	I	Rule 1	Annex II and III	17290107580233	61251, Circulating-fluid whole-body heating/cooling system pad, single-use