

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 |
| ThermoWrap®/CureWrap® | See Table-1 for list of Codes/Catalog Number |
| Intended Purpose | Basic UDI-DI |
| ThermoWrap®/ CureWrap® is intended to maintain preset body temperature as determined by a physician when used with the Allon® 2001/ CritiCool® and CritiCool® MINI systems | 08961280020000128J |

| RISK CLASS FOR DEVICES | | |
|------------------------|---|---|
| Device Classification | | Common Specifications |
| Class: | I | See Table-2 For List of Common Specifications and Table-3 for List of Standards |
| Rule: | I | |

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

- Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE:

TITLE: Director Quality Assurance and Regulatory Affairs

SIGNATURE: Lida Reed 

PLACE: Billerica, MA, USA

DATE: 18 January 2024

EC Declaration of Conformity

Table 1: Product names and Codes

| Product Name | EMDN Code |
|---|---|
| 500-03118 (Qty:1) Universal, Infant ThermoWrap®, 2.5–4.0Kg/45-53cm | Z12040208 – Body Thermoregulation Equipment |
| 524-03118 (Qty:24 x 500-03118/box) Universal, Infant ThermoWrap®, 2.5–4.0Kg/45-53cm | Z12040208 – Body Thermoregulation Equipment |
| 500-03121 (Qty:1) Infant ThermoWrap®, 4.0–7.0Kg/53-64cm | Z12040208 – Body Thermoregulation Equipment |
| 524-03121 (Qty:24 x 500-03121/box) Infant ThermoWrap®, 4.0–7.0Kg/53-64cm | Z12040208 – Body Thermoregulation Equipment |
| 500-03125 (Qty:1) Infant ThermoWrap®, 7.0–11Kg/64-79cm | Z12040208 – Body Thermoregulation Equipment |
| 524-03125 (Qty:24 x 500-03125/box) Infant ThermoWrap®, 7.0–11Kg/64-79cm | Z12040208 – Body Thermoregulation Equipment |
| 500-03131 (Qty:1) ThermoWrap® Universal, 79–91cm | Z12040208 – Body Thermoregulation Equipment |
| 506-03131 (Qty:6 x 500-03131/box) ThermoWrap® Universal, 79–91cm | Z12040208 – Body Thermoregulation Equipment |
| 512-03131 (Qty:12 x 500-03131/box) ThermoWrap® Universal, 79–91cm | Z12040208 – Body Thermoregulation Equipment |
| 500-03136 (Qty:1) ThermoWrap® Universal, 91–104cm | Z12040208 – Body Thermoregulation Equipment |
| 506-03136 (Qty:6 x 500-03131/box) ThermoWrap® Universal, 91–104cm | Z12040208 – Body Thermoregulation Equipment |
| 512-03136 (Qty:12 x 500-03131/box) ThermoWrap® Universal, 91–104cm | Z12040208 – Body Thermoregulation Equipment |
| 500-03141 (Qty:1) | Z12040208 – Body Thermoregulation Equipment |

EC Declaration of Conformity

| Product Name | EMDN Code |
|--|---|
| ThermoWrap® Universal, 104–122cm | |
| 506-03141 (Qty:6 x 500-03141/box) ThermoWrap® Universal, 104–122cm | Z12040208 – Body Thermoregulation Equipment |
| 512-03141 (Qty:12 x 500-03141/box) ThermoWrap® Universal, 104–122cm | Z12040208 – Body Thermoregulation Equipment |
| 500-03148 (Qty. 1) ThermoWrap® Universal, 122-135cm | Z12040208 – Body Thermoregulation Equipment |
| 506-03148 (Qty: 6 x 500-03148/box) ThermoWrap® Universal, 122-135cm | Z12040208 – Body Thermoregulation Equipment |
| 512-03148 (Qty: 12 x 500-03148/box) ThermoWrap® Universal, 122-135cm | Z12040208 – Body Thermoregulation Equipment |
| 500-03153 (Qty. 1) ThermoWrap® Universal, 135-152cm | Z12040208 – Body Thermoregulation Equipment |
| 506-03153 (Qty:6 x 500-03153/box) ThermoWrap® Universal, 135-152cm | Z12040208 – Body Thermoregulation Equipment |
| 512-03153 (Qty: 12 x 500-03153/box) ThermoWrap® Universal, 135-152cm | Z12040208 – Body Thermoregulation Equipment |
| 500-03160 (Qty. 1) ThermoWrap® Universal, 152-168cm | Z12040208 – Body Thermoregulation Equipment |
| 506-03160 (Qty: 6 x 500-03153/box) ThermoWrap® Universal, 152-168cm | Z12040208 – Body Thermoregulation Equipment |
| 512-03160 (Qty: 12 x 500-03160/box) ThermoWrap® Universal, 152-168cm | Z12040208 – Body Thermoregulation Equipment |
| 500-03166 (Qty. 1) ThermoWrap® Universal, 168-180cm | Z12040208 – Body Thermoregulation Equipment |
| 506-03166 (Qty: 6 x 500-03166/box) ThermoWrap® Universal, 168-180cm | Z12040208 – Body Thermoregulation Equipment |
| 512-03166 (Qty: 12 x 500-03166/box) | Z12040208 – Body Thermoregulation Equipment |

EC Declaration of Conformity

| Product Name | EMDN Code |
|--|---|
| ThermoWrap® Universal, 168-180cm | |
| 500-03363 (Qty. 1) ThermoWrap® Cardiac, 165-182cm | Z12040208 – Body Thermoregulation Equipment |
| 506-03363 (Qty: 6 x 500-03363/box) ThermoWrap® Cardiac, 165-182cm | Z12040208 – Body Thermoregulation Equipment |
| 512-03363 (Qty: 12 x 500-03363/box) ThermoWrap® Cardiac, 165-182cm | Z12040208 – Body Thermoregulation Equipment |
| 500-03500 (Qty. 1) CureWrap® Adult, 168-180cm | Z12040208 – Body Thermoregulation Equipment |
| 504-03500 (Qty: 4 x 500-03500/box) CureWrap® Adult, 168-180cm | Z12040208 – Body Thermoregulation Equipment |
| 508-03500 (Qty: 8 x 500-03500/box) CureWrap® Adult, 168-180cm | Z12040208 – Body Thermoregulation Equipment |
| 500-03518 (Qty. 1) CureWrap® Infant, 2.5-4Kg | Z12040208 – Body Thermoregulation Equipment |
| 504-03518 (Qty: 4 x 500-03518/box) CureWrap® Infant, 2.5-4Kg | Z12040208 – Body Thermoregulation Equipment |
| 508-03518 (Qty: 8 x 500-03518/box) CureWrap® Infant, 2.5-4Kg | Z12040208 – Body Thermoregulation Equipment |
| 500-03521 (Qty. 1) CureWrap® Infant, 4-7Kg | Z12040208 – Body Thermoregulation Equipment |
| 504-03521 (Qty: 4 x 500-03521/box) CureWrap® Infant, 4-7Kg | Z12040208 – Body Thermoregulation Equipment |
| 508-03521 (Qty: 8 x 500-03521/box) CureWrap® Infant, 4-7Kg | Z12040208 – Body Thermoregulation Equipment |
| 500-03525 (Qty. 1) CureWrap® Infant, 7-11Kg | Z12040208 – Body Thermoregulation Equipment |

EC Declaration of Conformity

| Product Name | EMDN Code |
|---|---|
| 504-03525 (Qty: 4 x 500-03525/box) CureWrap® Infant, 7-11Kg | Z12040208 – Body Thermoregulation Equipment |
| 508-03525 (Qty: 8 x 500-03525/box) CureWrap® Infant, 7-11Kg | Z12040208 – Body Thermoregulation Equipment |
| 500-03531 (Qty. 1) CureWrap® Pediatric, 79-91cm | Z12040208 – Body Thermoregulation Equipment |
| 504-03531 (Qty: 4 x 500-03531/box) CureWrap® Pediatric, 79-91cm | Z12040208 – Body Thermoregulation Equipment |
| 508-03531 (Qty: 8 x 500-03531/box) CureWrap® Pediatric, 79-91cm | Z12040208 – Body Thermoregulation Equipment |
| 500-03536 (Qty. 1) CureWrap® Pediatric, 91-104cm | Z12040208 – Body Thermoregulation Equipment |
| 504-03536 (Qty: 4 x 500-03536/box) CureWrap® Pediatric, 91-104cm | Z12040208 – Body Thermoregulation Equipment |
| 508-03536 (Qty: 8 x 500-03536/box) CureWrap® Pediatric, 91-104cm | Z12040208 – Body Thermoregulation Equipment |
| 500-03541 (Qty. 1) CureWrap® Pediatric, 104-122cm | Z12040208 – Body Thermoregulation Equipment |
| 504-03541 (Qty: 4 x 500-03541/box) CureWrap® Pediatric, 104-122cm | Z12040208 – Body Thermoregulation Equipment |
| 508-03541 (Qty: 8 x 500-03541/box) CureWrap® Pediatric, 104-122cm | Z12040208 – Body Thermoregulation Equipment |
| 500-03548 (Qty. 1) CureWrap® Pediatric, 122-135cm | Z12040208 – Body Thermoregulation Equipment |
| 504-03548 (Qty: 4 x 500-03548/box) CureWrap® Pediatric, 122-135cm | Z12040208 – Body Thermoregulation Equipment |
| 508-03548 (Qty: 8 x 500-03548/box) | Z12040208 – Body Thermoregulation Equipment |

EC Declaration of Conformity

| Product Name | EMDN Code |
|--|---|
| CureWrap® Pediatric, 122-135cm | |
| PED-SM008 (Qty: 4 x 500-03518 and 4 x 500-03521) CureWrap® Pediatric Small/Infant Assorted | Z12040208 – Body Thermoregulation Equipment |
| PED-MD008 (Qty: 4 x 500-03525 and 4 x 500-03531) CureWrap® Pediatric, Medium Assorted | Z12040208 – Body Thermoregulation Equipment |
| PED-LA008 (Qty: 4 x 500-03536 and 4 x 500-03541) CureWrap® Pediatric, Large Assorted | Z12040208 – Body Thermoregulation Equipment |
| PED-XL008 (Qty: 4 x 500-03548 and 4 x 500-03500) CureWrap® Pediatric, X-Large Assorted | Z12040208 – Body Thermoregulation Equipment |

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

| Common Specification | Title | Version |
|----------------------|-------|---------|
| N/A | N/A | N/A |

EC Declaration of Conformity

Table 3: Standards applied in full or in part.

| Standards | Title | Version |
|----------------|---|-------------------------------|
| ISO 13485 | Medical devices. Quality management systems. Requirements for regulatory purposes | 2016/A11 Edition (2021) |
| ISO 14971 | Medical devices. Application of risk management to medical devices | 2019/A11 Edition (2021) |
| IEC 62366-1 | Medical devices. Application of usability engineering to medical devices. | 2015/A1 Edition (2020) |
| ISO 20417 | Medical devices. Information to be supplied by the manufacturer | 2021 Edition (2021) |
| ISO 15223-1 | Medical devices. Symbols to be used with information to be supplied by the manufacturer. General requirements. | 2021 Edition (2021) |
| ISO 10993-1 | Biological evaluation of medical devices. Evaluation and testing within a risk management process. | 2020 Edition (2020) |
| ISO 10993-5 | Biological evaluation of medical devices. Tests for in vitro cytotoxicity | 2009 Edition (2009) |
| ISO 10993-10 | Biological evaluation of medical devices. Tests for skin sensitization. | 2023 Edition (2023) |
| ISO 10993-11 | Biological evaluation of medical devices. Tests for systemic toxicity. | 2018 ED. Corrigendum 1 (2022) |
| ISO 10993-23 | Biological evaluation of medical devices. Tests for irritation. | 2021 Edition (2021) |
| ASTM D4332 | Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing | 2022 Edition (2022) |
| ASTM D4169 | Standard Practice for Performance Testing of Shipping Containers and Systems | 2022 Edition (2022) |
| IEC 80601-2-35 | Medical electrical equipment. Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use | 2009/A1 Edition (2017) |