



## Declaration of Conformity

| PRODUCT IDENTIFICATION                       |              |
|--|--------------|
| Product name                                 | Model/number |
| HotDog® Temperature Management System Cables | See Page 2   |

| MANUFACTURER                         |   |   |
|--------------------------------------|---|---|
| Name of company                      | Address   | Representative  |
| Augustine Temperature Management LLC | Corporate<br>6581 City West Parkway<br>Eden Prairie, MN 55344<br>USA<br><br>Manufacturing<br>7656 W. 78 <sup>th</sup> St.<br>Minneapolis, MN 55439<br>USA | Ivona Domnisoru<br>Quality & Regulatory Representative<br><br>1.952.465.3539 phone<br>1.952.465.3501 fax<br>idomnisoru@augurg.com |
| SRN                                  | US-MF-000020611   |   |

| AUTHORIZED REPRESENTATIVE |   |   |
|---------------------------|---|---|
| Name of company           | Address   | Telephone/email                           |
| Emergo Europe             | Westervoortsedijk 60<br>6827 AT Arnhem<br>The Netherlands | +31.70.345.8570<br>europe@emergogroup.com |
| SRN                       | NL-AR-000000116   |   |

| CONFORMITY ASSESSMENT |  |   |
|-----------------------|--|---|
| Device classification | Route to compliance  | Standards applied   |
| Class I<br>Rule 1     | Annex I, II, III of EU Medical Device Regulation<br>2017/745 | ISO 13485:2016 Certificate: FM 504729<br>Annex I EU Medical Device Regulation<br>2017/745 |
| RoHS Declaration      | Compliant with RoHS-3 Directive 2015/863/EU                  |   |
| Intended Purpose      | Hardware accessory for connecting devices                    |   |
| Basic UDI-DI          | 0855913001HDTMSC57   |   |

Augustine Temperature Management declares that the above-mentioned products meet the provision of the EU Medical Device Regulation 2017/745 as transposed in the national laws of the Member States. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

**COMPANY REPRESENTATIVE:** Ivona Domnisoru

**TITLE:** Quality & Regulatory Representative

**PLACE:** Eden Prairie, Minnesota USA

**SIGNATURE:**

**DATE:** October 12, 2023



| <b>HotDog Temperature Management System Cable Model List</b> |   |
|--|---|
| <b>Catalog Number</b>  | <b>Description</b>                                |
| A101   | Cable, Blanket, 4 Meter Yellow                    |
| A112   | Cable, Mattress, 5 Meter Blue                     |
| A410-OUT   | 3.5mm to Two-pin Rectangle Cable                  |
| A411-IN  | Interconnect Cable (3.5mm TRSM-TRSF) 2m           |
| A412-IN  | Two-pin Rectangle Temperature Probe Adapter Cable |