

# Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	Model/number
HotDog® Patient Warming System	See Page 2

MANUFACTURER		
Name of company	Address	Representative
Augustine Temperature Management LLC	Corporate 6581 City West Parkway Eden Prairie, MN 55344 USA  Manufacturing 7656 W. 78 <sup>th</sup> St. Minneapolis, MN 55439 USA	Temi Ogunse Regulatory/Quality Representative  1.952.465.3539 phone 1.952.500.9329 fax togunse@aug Surg.com

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class IIb Rule 9	MDD 93/42/EEC Council Directive, Annex II, exclusion Section 4	MDD 93/42/EEC CE Certificate: CE 504949 BS EN ISO 13485:2016 Certificate: FM 504729 Notified Body: BSI (2797)

**Augustine Temperature Management** declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.

**COMPANY REPRESENTATIVE:** Temi Ogunse

**TITLE:** Regulatory/Quality Representative  
**DATE:** 31Mar2021

**SIGNATURE:**



<b>HotDog Product List</b>	
<b>Catalog Number</b>	<b>Description</b>
WC01	Controller Single-Port
WC02	Controller Single-Port
WC51	Controller Multi-Port
WC52	Controller Multi-Port
WC71	Temperature Management Controller Single-Port
WC77	Temperature Management Controller Multiport
B103	Lower Body Warming Blanket
B104	Full Body Warming Blanket
B105	Multi-Position Warming Blanket
B107	Head Warming Wrap
B108	Lower Body Warming Blanket, no flaps
B110	Torso Warming Blanket, V-Shaped
B203	Pediatric Lower Body Warming Blanket
B270	Pediatric Head Warming Wrap
B271	Pediatric Head Warming Wrap
B500	Universal Warming Blanket
U101	Under Body Warming Mattress (20 in. x 32 in.)
U102	Under Body Warming Mattress (20 in. x 50 in.)
U220	Pediatric Warming Mattress (17.5 in x 29 in)
U300	Under Body Warming Mattress for Trendelenburg Positioning (20 in. x 36 in.)