

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 th 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: 10May2021

SIGNATURE:



HotDog Product List	
Catalog Number	Description
WC01	HotDog Patient Warming Controller
WC02	HotDog Patient Warming Controller
WC51	HotDog Multifunction Warming Controller
WC52	HotDog Multifunction Warming Controller
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
B110	Torso Warming Blanket
B203	Pediatric Lower Body Warming Blanket
B270	Small Pediatric Head Warming Wrap
B271	Large Pediatric Head Warming Wrap
B500	Universal Warming Blanket
U101	Under Body Warming Mattress 82 cm (32")
U102	Under Body Warming Mattress 127 cm (50")
U220	Pediatric Underbody Warming Mattress
U300	Trendelenburg Warming Mattress, 89 cm (35")