

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	Model/number
Hot Dog® 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 Quality/Regulatory 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 ISO13485:2003 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: Quality/Regulatory Representative
DATE: 22Sep2020

SIGNATURE:



Hot Dog Product List	
Catalog Number	Description
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
U300	Under Body Warming Mattress for Trendelenburg Positioning (20 in. x 36 in.)
U501	Underbody Warming Mattress + Return Electrode, 19.5" x 32"
U502	Underbody Warming Mattress + Return Electrode, 19.5" x 50"
U522	Pediatric Underbody Warming Mattress + Return Electrode 17.5' x 29"
U530	Trendelenburg Position Warming Mattress + Return Electrode 23"x39.25"
U103	Underbody Mattress – extended 78"