

# Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	Model/number
Hot Dog® Patient Warming System, Single Use Sheets and Accessories	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 Quality & Regulatory Representative  1.952.465.3539 phone 1.952.465.3501 fax togunse@augbiomed.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 I Rule 4	Annex IX, Section III, Rule 4 of MDD 93/42/EEC Council Directive	CE Certificate: CE 504949 ISO13485:2003 Certificate: FM 504729 Annex I MDD 93/42/EEC

**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:** 22Sep20

**SIGNATURE:**





**Augustine Temperature Management LLC Product Listing for Declaration of Conformity**

Hot Dog Product List	
Catalog Number	Description
S104	Full Body Disposable Sheet
A300	Wafflegrip Trendelenburg Positioning Kit
A301	Wafflegrip Trendelenburg BackSaver Slide Sheet