

MANUFACTURER'S DECLARATION OF CONFORMITY
AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002
FULL QUALITY ASSURANCE PROCEDURE

This is a declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian *Therapeutic Goods (Medical Devices) Regulations 2002* relating to the stated devices. Reference attached table.

Reference: Product Schedule, Hot Dog Patient Warming System

Manufacturer's Name: Augustine Temperature Management LLC

Business Address: 6581 City West Parkway
Eden Prairie, MN 55344 USA

Medical Device(s): Hot Dog Patient Warming System - Reference attached table for products

Classification: Class IIb

GMDN Code and Term: 37329 Heating Unit, Pad, Electric, System

Scope of Application: Design and manufacture of patient warming systems

Full Quality Management System Certificate:

Assessment Body: BSI Americas
ISO 13485 FM Number: 504729

Design Examination Certificate:

Assessment Body: BSI Americas
CE Certificate Number: 504949

Standards Applied:

ISO 13485—Quality management systems: Requirements for regulatory purposes
ISO 14971—Application of risk management to medical devices
ISO 10993—Biological evaluation of medical devices
ISO 60601—Medical electrical equipment

Authorized Signatory:



Temi Ogunse
RA/QA Representative

Date: 10/27/2020

Product Schedule, Hot Dog Patient Warming System
Attachment to Declaration of Conformity (Australia)

HotDog® 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.)
U103	Underbody Mattress – extended 78"
A101	Cable, Warming Blanket, 4 Meter
A112	Cable, Warming Mattress, 5 Meter