

**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 6.6 schedule 3, Part 6 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 Temperature Management System

**Classification:** Class IIb

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

**Scope of Application:** The Design and Manufacture of Patient Temperature Management Systems and Related nonsterile accessories including Warming Mattresses with Electrosurgical Grounding Pads

**Full Quality Management System Certificate:**

**Assessment Body:** BSI Americas  
**ISO 13485 FM Number:** 504729  
**MDSAP Number:** 715042

**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:**



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Ivona Domnisoru  
RA/QA Representative

Date: 8/17/2022

**Hot Dog Temperature Management System  
Attachment to Declaration of Conformity (Australia)**

<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
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	Underbody Warming Mattress (80 cm (32"))
U102	Underbody Warming Mattress 127 cm (50"))
U220	Pediatric Underbody Warming Mattress
U300	Trendelenburg Warming Mattress 89 cm (35"))