

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 Biomedical + Design LLC
Db a 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:



Andreas Deibel
Vice President of Operations

Date: 5-25-2012

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

HotDog® Patient Warming Product List	
Catalog Number	Description
WC01	HotDog® Controller
WC02	HotDog® Controller
WC51	HotDog® Multifunction Controller
WC52	HotDog® Multifunction Controller
B103	Lower Body Warming Blanket
B104	Full Body Warming Blanket
B105	Multi-position Warming Blanket
B107	Head Warming Blanket
B108	Warming Blanket, 70 x 100cm
B110	Torso Warming Blanket
U101	Underbody Warming Mattress, 50 x 82cm
U102	Underbody Warming Mattress, 50 x 127cm
A101	Cable, Warming Blanket, 4 meter
A112	Cable, Warming Mattress, 5 meter