



DECLARATION OF CONFORMITY
Medical Devices



Manufacturer

Augustine Biomedical + Design
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Dba Augustine Temperature Management LLC
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We ensure and declare that the distributed CE marked products, as specified below and falling within Class IIb, meet the applicable provisions of the EC-Directive.

This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II excluding Section 4 of the EC-Directive. The conformity of the full quality assurance system set out in Annex II, is described in EC Certificate reference number: 504949, issued and delivered by BSI Product Services.

The standards used to show compliance with the EC Directive Essential Requirements are identified in the Augustine Essential Requirements checklist Document # D1101

This declaration is valid for all products described below, bearing the CE marking and manufactured by Augustine Biomedical + Design.

Product Information

Name:	Hot Dog™ Patient Warming System
Product and Catalog Numbers:	See product list below
Regulatory Classification:	Class IIb medical device per Council Directive 93/42/EEC, Annex IX, Section III, Rule 9.
Place and Original Date of Issue:	Eden Prairie, Minnesota, USA; October 29, 2014

Signature: Jasper E. Blake, RA/QA Lead

Hot Dog Product List	
Catalog Number	Description
WC01	Hot Dog Controller
WC02	Hot Dog Controller
WC51	Hot Dog Multifunction Controller
WC52	Hot Dog Multifunction Controller
B103	Lower Body Blanket
B104	Full Body Blanket
B105	Multi-position Blanket
B107	Head Warming Blanket
B108	70cm x 100cm Warming Blanket
B110	Torso Blanket
U101	Small Warming Mattress
U102	Med Warming Mattress
U103	Large Warming Mattress