

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 504949
Issued To: **Augustine Biomedical + Design, LLC.**
dba Augustine Temperature Management
6581 City West Parkway
Eden Prairie
Minnesota
55344
USA

In respect of:

The design and manufacture of patient warming systems

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **09 January 2007**

Date: **19 December 2016**

Expiry Date: **08 January 2022**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	Service(s) supplied
Augustine Biomedical + Design, LLC dba Augustine Temperature Management 7656 West 78th Street Bloomington Minnesota 55439 USA	Final Inspection Manufacture Testing
Emergo Europe Molenstraat 15 2513 BH, The Hague Netherlands	EU Representative
Sparton Corporation 2920 Kelly Avenue Watertown South Dakota 57201-7249 USA	Final Inspection Manufacture Testing

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
9 January 2007	4805871	First Issue
29 October 2008	7246430	Re-issue due to the change of company name from 'Augustine Biomedical + Design LLC' to 'Augustine Biomedical + Design LLC, dba Hot Dog International LLC'
22 December 2011	7650686 7728276	Change of company from 'Augustine Biomedical + Design, LLC, dba Hot Dog International LLC' to 'Augustine Biomedical + Design, LLC, dba Augustine Temperature Management'. Addition of EU Representative. Certificate renewal. Change of subcontractor name from 'OEM Worldwide' to 'Onyx EMS, LLC'
19 December 2016	8602967	Renewal of CE 504949 Addition of new site 'Augustine Biomedical + Design, LLC dba Augustine Temperature Management 7656 West 78th Street, Bloomington, MN 55439 USA' for final inspection, manufacture and testing activities. Change of 'Onyx EMS, LLC' significant subcontractor details to 'Sparton Corporation'