

EC Certificate - Full Quality Assurance System

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

No. CE 504949
Issued To: **Augustine Temperature Management, LLC**
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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2007-01-09**

Date: **2019-03-21**

Expiry Date: **2022-01-08**

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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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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

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 Temperature Management, LLC
7656 W 78th Street
Mineapolis
Minnesota
55439
USA

Final Inspection
Manufacture
Testing

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The 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'.

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Date	Reference Number	Action
25 September 2017	8768622	Change of legal manufacturer name details, removal of 'Augustine Biomedical+Design LLC. dba'. Change of EU Rep details to 'Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, The Netherlands'. Change in 'Augustine Temperature Management, LLC' address details in the significant subcontractor list. Change in Legal manufacturer name details to add 'LLC'.
Current	7781911	Traceable to NB 0086.

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