

Full Quality Assurance

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 under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

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

Rob Wallis, Chair Certification Body Management Committee

First Issued: **9 Jan 2007**

Date: **22 Dec 2011**

Expiration Date: **8 Jan 2017**

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Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

List of Significant Subcontractors

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

Certificate No. **CE 504949**
Date: **22 Dec 2011**
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Subcontractor	Service(s) supplied
Emergo Europe Molenstraat 15 2513 BH The Hague Netherlands	EU Representative
Onyx EMS, LLC 2920 Kelly Avenue Watertown SD 57201 USA	Final Inspection Manufacture Testing

History of Quality Assurance Certificate

Certificate No: CE 504949
Issue Date: 22 Dec 2011
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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'