

bsi.

Certificate

Full Quality Assurance

No. CE 68983



Issued to:

**EUROMED, Inc.
25 Corporate Drive
Orangeburg
New York
10962
USA**

In respect of:

The design, development and manufacture of SureSkin® and other Hydrocolloid Wound Dressings

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):

Gary Fenton, Global Assurance Director

First Issued: **5 Mar 2003**

Date: **25 Mar 2013**

Expiration Date: **5 Mar 2018**

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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.

...making excellence a habit.™

List of Significant Subcontractors

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

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Subcontractor	Service(s) supplied
Synergy Health AST, LLC 6750 East 46th Avenue Drive Suite 100 Denver Colorado 80216 USA	E beam Sterilization
Synergy Health AST, LLC 7225 North Noah Drive Saxonburg Pennsylvania 16056 USA	E beam Sterilization
Roland Healthcare ApS Hvidehusvej 34 DK-3450 Allerød Denmark	EU Representative
Synergy Health AST, LLC 500 West 4th Street Lima Ohio 45804 USA	E beam Sterilization



Certificate

History of Quality Assurance Certificate

Certificate No: CE 68983
Issue Date: 25 Mar 2013
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Date	Reference Number	Action
05 March 2003		First Issue
31 July 2003		Additional Sub-contractor
19 December 2006	4924717	Removal of 'sale' from the scope. Removal of Titan Scan Technologies as a subcontractor. Addition of Sterigenics (Rockaway, NJ) as a subcontractor for Gamma Irradiation. Addition of BeamOne LLC (Ohio) as a subcontractor for E Beam Sterilization. Certificate reissued in new format
21 June 2007		Change of address from New Jersey to New York. Amendment to subcontractor E-Beam Services, Inc address from 32 Melrich Road to 118 Melrich Road
6 March 2008	7176310	Certificate renewal
16 August 2011	7717654	Removal of subcontractor E-Beam Services, NJ. Addition of BeamOne LLC locations in Denver, CO and Saxonburg, PA for the activity of e-beam sterilisation. Addition of EU Reps: Roland Healthcare ApS and Emergo Europe



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Date	Reference Number	Action
25 March 2013	7943324	Change of name of significant subcontractor BeamOne LLC (Colorado 80216, Pennsylvania 16056 and Ohio 45804 locations) to Synergy Health AST, LLC. Removal of significant subcontractors Sterigenics and Emergo Europe. Certificate renewal