

# EC Certificate - Full Quality Assurance System

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

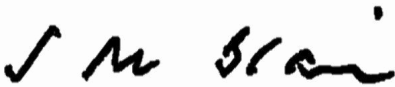
**No.** CE 68983  
**Issued To:** **EUROMED, Inc.**  
**25 Corporate Drive**  
**Orangeburg**  
**New York**  
**10962**  
**USA**

In respect of:

**The design, development and manufacture of SureSkin<sup>®</sup> and other Hydrocolloid Wound Dressings**

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):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **2003-03-05**

Date: **2018-02-23**

Expiry Date: **2023-03-05**

...making excellence a habit.™

Page 1 of 1

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.

# EC Certificate - Full Quality Assurance System

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:

Certificate No: **CE 68983**  
Date: **2018-02-23**  
Issued To: **EUROMED, Inc.**  
**25 Corporate Drive**  
**Orangeburg**  
**New York**  
**10962**  
**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Isomedix Operations, Inc. 2 Nucifora Boulevard Chester New York 10918 USA	<b>E Beam Sterilization</b>
Roland Healthcare ApS Hvidehusvej 34 DK-3450 Allerød Denmark	<b>EU Representative</b>
Synergy Health AST, LLC 6750 East 46th Avenue Drive Suite 100 Denver Colorado 80216 USA	<b>E Beam Sterilization</b>

...making excellence a habit.™

# EC Certificate - Full Quality Assurance System

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:

Certificate No: **CE 68983**  
Date: **2018-02-23**  
Issued To: **EUROMED, Inc.**  
**25 Corporate Drive**  
**Orangeburg**  
**New York**  
**10962**  
**USA**

**Subcontractor:**

**Service(s) supplied**

---

Synergy Health AST, LLC  
7225 North Noah Drive  
Saxonburg  
Pennsylvania 16056  
USA

**E Beam Sterilization**

---

Synergy Health AST, LLC  
500 West 4th Street  
Lima  
Ohio  
45804  
USA

**E Beam Sterilization**

...making excellence a habit.™

# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 68983**  
 Date: **2018-02-23**  
 Issued To: **EUROMED, Inc.**  
**25 Corporate Drive**  
**Orangeburg**  
**New York**  
**10962**  
**USA**

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 Emurgo Europe
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 Emurgo Europe.

# EC Certificate - Full Quality Assurance System

## Certificate History

Certificate No: **CE 68983**  
 Date: **2018-02-23**  
 Issued To: **EUROMED, Inc.**  
**25 Corporate Drive**  
**Orangeburg**  
**New York**  
**10962**  
**USA**

Date	Reference Number	Action
Current	8905609	Certificate renewal Addition of Isomedix Operations, Inc. as significant subcontractor for E-Beam sterilisation.

...making excellence a habit.™

Page 2 of 2

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.