

# EC Certificate - Full Quality Assurance System

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

**No.****CE 583824**

## Issued To:

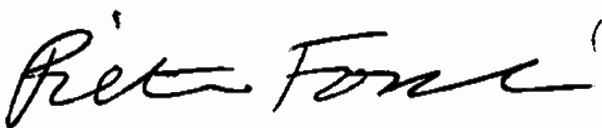
**Preservation Solutions, Inc.  
1099 Proctor Drive  
Elkhorn  
Wisconsin  
53121  
USA**

In respect of:

**The design, development and manufacture of sterile solutions for the preservation of organs for transplantation and sterile fabric based devices for temporary bridging of abdominal wall openings**

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):



Pietro Foschi - Strategic Delivery Director

First Issued: **30 July 2012**Date: **27 March 2015**Expiry Date: **29 July 2017**

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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.

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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:

Certificate No: **CE 583824**  
Date: **27 March 2015**  
Issued To: **Preservation Solutions, Inc.**  
**1099 Proctor Drive**  
**Elkhorn**  
**Wisconsin**  
**53121**  
**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Emergo Europe Molenstraat 15 2513 BH The Hague Netherlands	<b>EU Representative</b>
Geneva Laboratories 1001 Proctor Drive Elkhorn WI 53121 USA	<b>Laboratory Service Testing</b>
Medline Industries, Inc. 1200 Townline Road One Medline Place Mundelein Illinois 60060-4486 USA	<b>ETO Sterilization</b>

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**53121**  
**USA**

**Subcontractor:**

**Service(s) supplied**

Research Products, Inc  
410 N. Business Center  
Mount Prospect  
IL 60056  
USA

**Crucial Supplier**

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 583824**  
 Date: **27 March 2015**  
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 1099 Proctor Drive  
 Elkhorn  
 Wisconsin  
 53121  
 USA**

Date	Reference Number	Action
30 July 2012	7653627	First issue.
27 March 2015	8238270	Change of address. Addition of significant subcontractors 'Research Products, Inc Illinois' and 'Geneva Laboratories, Wisconsin'.

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Page 1 of 1

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