

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**

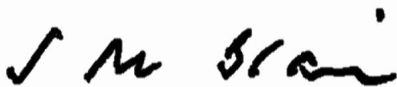
In respect of:

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.

Those aspects of Annex II relating to securing and maintaining sterility in the manufacture of suture retention devices.

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: **2012-07-30**Date: **2017-07-27**Expiry Date: **2022-07-29**

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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.

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List of Significant Subcontractors

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

Certificate No: **CE 583824**
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USA

Subcontractor:	Service(s) supplied
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	EU Representative
Geneva Laboratories 1001 Proctor Drive Elkhorn WI 53121 USA	Testing
Medline Industries, Inc. 1200 Townline Road One Medline Place Mundelein Illinois 60060-4486 USA	ETO Sterilization

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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**
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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'.
14 October 2016	8570403	Addition of suture retention devices.
Current	8717590 8775806	Certificate renewal. Update to EU authorized representative address

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