By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 571124**

Issued To: **Polymer Science, Inc.**
2787 S. Freeman Road
Monticello
Indiana
47960
USA

In respect of:

The design, development, manufacture and final inspection of sterile hydrogel chest seal 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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2011-02-22** Date: **2020-12-18** Expiry Date: **2024-05-26**

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Supplementary Information to CE 571124

Issued To:

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NBOG code(s)	Device description	Intended purpose
Class IIb		
MD0301	Hydrogel Chest Seal Wound Dressing	Field treatment for an open pneumo-thoracic injury resulting from penetrating chest trauma.

First Issued: **2011-02-22** Date: **2020-12-18** Expiry Date: **2024-05-26**

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List of Significant Subcontractors

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

Certificate No:	**CE 571124**
Date:	**2020-12-18**
Issued To:	**Polymer Science, Inc.** **2787 S. Freeman Road** **Monticello** **Indiana** **47960** **USA**

Subcontractor:	**Service(s) supplied**
mdi Europa GmbH Langenhagener Str. 71 Langenhagen 30855 Germany	**EU Representative**
Polymer Science, Inc 2787 S. Freeman Road Monticello Indiana 47960 USA	**Manufacture**
Sterigenics US, LLC 305 Enterprise Drive Westerville Ohio 43081 USA	**Radiation (Gamma Sterilization)**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 571124**

Date: **2020-12-18**

Issued To: **Polymer Science, Inc.**
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Date	Reference Number	Action
22 February 2011	7632629	First issue, transfer from another Notified Body.
06 June 2016	8482580	Certificate renewal. Change of European Representative from Fenton Pharmaceuticals Ltd. to Polymer Science Europe GmbH. Removal of Polymer Sciences, Inc. at the 3019 S. Freeman Road site from list of significant subcontractor. Addition of Polymer Science, Inc. at the 2577 S. Freeman Road site to list of significant subcontractor. Addition of 'sterile' to the scope expression.
05 April 2017	8694931	Change of primary packaging and sterilisation method from ETO to gamma. Addition of gamma sterilisation sub-contractor Sterigenics US, LLC. Removal of ETO sterilisation sub-contractor STERIS Isomedix Services, Inc. Administrative amendment to scope to remove brand name (Bolin) and clarify the device technology (hydrogel).

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Date	Reference Number	Action
26 February 2019	8405710	Traceable to NB 0086.
07 November 2019	3040378	Certificate renewal. Update to Sterigenics Ohio name and address. Addition of product supplementary information table.
Current	3329969	Removal of Polymer Science Europe GmbH as EU Representative. Addition of mdi Europe GmbH as EU Representative. Update LM address to 2577 S. Freeman Road. Remove significant subcontractor Polymer Science 2577 S. Freeman Road and replace with Polymer Science 2787 S. Freeman Road as significant subcontractor for manufacture