By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 744264 R000

Manufacturer: Speciality Fibres and Materials Ltd.

Address:
Galaxy House
31 Herald Way
Binley Industrial Estate
Coventry
CV3 2RQ
United Kingdom

Single Registration Number: GB-MF-000004153

EU Authorised Representative: Advena Ltd

Address:
Tower Business Centre
2nd Floor, Tower Street
Swatar
BKR 4013
Malta

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-05-12** Date: **2022-05-12** Expiry Date: **2027-05-11**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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Device Schedule: Class IIb devices

Class IIb	Intended purpose
Calcium alginate and calcium alginate / cellulose wound dressings including rope format	For the treatment of acute and chronic wounds which are moderate to heavily exuding, superficial or deep

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3386914	Issued

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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 744264 R000

Date: **2022-05-12**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Lohmann & Rauscher GmbH Kirchengasse 17 2525 Schönau a.d. Triesting Austria	**Control of Sterilization** **Packaging**
Mediscan GmbH & Co KG Im Forschungszentrum A-2444 Seibersdorf a.d. Leitha Austria	**Radiation (Gamma Sterilization)**

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