By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 620062**

Issued To: **Speciality Fibres and Materials Ltd**
101 Lockhurst Lane
Coventry
CV6 5SF
United Kingdom

In respect of:

The design, development and manufacture of sterile cellulose based 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: **2015-06-08** Date: **2019-10-04** Expiry Date: **2024-05-26**

...making excellence a habit.™

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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 620062

Issued To:

Speciality Fibres and Materials Ltd
101 Lockhurst Lane
Coventry
CV6 5SF
United Kingdom

NBOG code(s)	Device description	Intended purpose
Class IIb		
MD0301	Sterile cellulose based wound dressing	For use on moderate to heavily exuding acute and chronic wounds. For use on lower leg ulcers, pressure ulcers, diabetic ulcers, surgical wounds, partial thickness burns, traumatic wounds and oncology wounds. Can be used with a secondary dressing

First Issued: **2015-06-08** Date: **2019-10-04** Expiry Date: **2024-05-26**

...making excellence a habit.™

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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.