

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**
Galaxy House
31 Herald Way
Binley Industrial Estate
Coventry
CV3 2RQ
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**

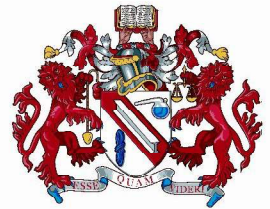
Date: **2021-01-08**

Expiry Date: **2024-05-26**

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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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Supplementary Information to CE 620062

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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

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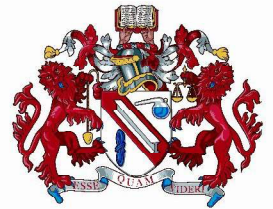
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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.



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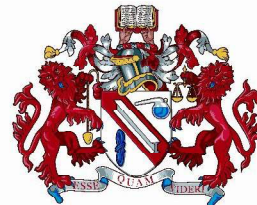
List of Significant Subcontractors

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

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CV3 2RQ
United Kingdom

Subcontractor:	Service(s) supplied
Advena Limited Tower Business Centre 2nd Floor, Tower Street Swatar BKR 4013 Malta	EU Representative
Flexible Medical Packaging Ltd Unit 6A Middlegate White Lund Industrial Estate Morecambe LA3 3BN United Kingdom	Packaging
Flexible Medical Packaging Ltd Unit 8-10 Hightown Whitecross Industrial Estate Lancaster Lancashire LA1 4XS United Kingdom	Packaging

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Subcontractor:

Service(s) supplied

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

Manufacture

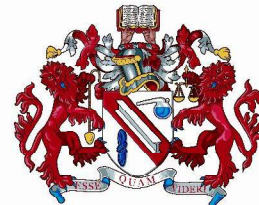
STERIS Applied Sterilization Technologies
 Moray Road
 Elgin Industrial Estate
 Swindon
 SN2 8XS
 United Kingdom

Radiation (Gamma Sterilization)

Synergy Health Sterilisation UK Ltd
 (Synergy Health - AST - Bradford)
 Roydsale Way
 Euroway Industrial Estate
 Bradford
 BD 6SE
 United Kingdom

Radiation (Gamma Sterilization)

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Certificate History

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Date	Reference Number	Action
08 June 2015	8224705	First issue.
17 November 2016	8635683	Addition of Synergy Health Sterilisation UK Ltd (Synergy Health – AST – Swindon) as significant sub-contractor for gamma sterilisation.
25 September 2017	8775502	Addition of significant subcontractor Flexible Medical Packaging Limited (Morecambe) for packaging. Removal of Chester Medical Solutions as a significant subcontractor for packaging.
30 May 2018	8918942	Addition of the critical subcontractor Speciality Fibres and Materials Ltd, Galaxy House. Synergy Health Sterilisation, Swindon, name change to Steris Applied Sterilization Technologies.
05 March 2019	8846847	Traceable to NB 0086.
04 October 2019	9771302	Certificate Renewal and addition of Supplementary Device Table.
13 May 2020	9756633	Change of Legal Manufacturer address to Galaxy House, 31 Herald Way, Binley Industrial Estate, Coventry CV3 2RQ. Removal of Speciality Fibres and Materials Ltd. Galaxy House as critical subcontractor. Addition of Speciality Fibres and Materials Ltd. 101 Lockhurst Lane as critical subcontractor for manufacture.
Current	3347821	Addition of Advena Limited, Malta as EU Representative

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