By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 522460**

Issued To: **STERIS Corporation**
2720 Gunter Park Drive East
Montgomery
Alabama
36109
USA

In respect of:

Those aspects of Annex V concerned with securing and maintaining sterile conditions of handle and camera covers for surgical lighting systems

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

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

Albert Roossien, Regulatory Lead

First Issued: **2007-08-01** Date: **2019-01-03** Expiry Date: **2019-11-08**

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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.

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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Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No:	**CE 522460**
Date:	**2019-01-03**
Issued To:	**STERIS Corporation** **2720 Gunter Park Drive East** **Montgomery** **Alabama** **36109** **USA**

Subcontractor:	**Service(s) supplied**
Fremont Plastics 500 W, Waterstreet Fremont Indiana 46737 USA	**Manufacture**
Steris Isomedix Services 4405 Marketing Place Groveport Ohio 43125 USA	**Gamma Irradiation**
STERIS Isomedix Services 2072 Southport Road Spartanburg South Carolina 29306 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
STERIS Ltd. Chancery House 190 Waterside Road Hamilton Industrial Park Leicester LE5 1QZ United Kingdom	**EU Representative**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 522460**

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Date	Reference Number	Action
1 August 2007		First Issue. Transfer from Intertek ETL SEMKO Annex V Certificate Number 41314754.
31 August 2007		Reissue due to addition of Advanced Medical Designs, Inc and Sterigenics as significant subcontractors.
22 October 2009	7445424	Certificate renewal. The removal of Advanced Medical Designs, Inc and Sterigenics as significant sub-contractors.
28 September 2012	7905780	Replacement of EU Representative with STERIS Ltd., Leicester, UK and rewording of scope.
16 September 2014	8198223	Renewal of Certificate.
25 November 2015	8426523	Addition of STERIS Isomedix Services, Spartanburg, South Carolina as a significant subcontractor for EtO sterilization.
Current	7782023	Traceable to NB 0086.

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