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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2007-08-01** Date: **2019-10-10** Expiry Date: **2024-05-26**

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Supplementary Information to CE 522460

Issued To:

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Number	Device Name	Intended purpose per IFU
Class I sterile		
MD 0106 MDS 7006	Sterile Light Handle Cover	N/A
MD 0106 MDS 7006	Sterile Camera Handle Cover	N/A

First Issued: **2007-08-01** Date: **2019-10-10** Expiry Date: **2024-05-26**

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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:	**2019-10-10**
Issued To:	**STERIS Corporation** **2720 Gunter Park Drive East** **Montgomery** **Alabama** **36109** **USA**

Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. 2072 Southport Road Spartanburg South Carolina 29306 USA	**ETO Sterilization**
STERIS Ireland Limited IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland	**EU Representative**
TEQ Fremont 500 W. Waterstreet Fremont Indiana 46737 USA	**Manufacture**

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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.
03 January 2019	7782023	Traceable to NB 0086.

EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
Current	9732497	Certificate renewal. Change name of subcontractor Fremont Plastics to TEQ Fremont. Change name of sub-contractors STERIS Isomedix Services to Isomedix Operations, Inc. Change EU Representative from STERIS Ltd, to STERIS Ireland Limited. Removed obsolete subcontractor, Steris Isomedix Services, 4405 Marketing Place, Groveport, Ohio, 43125, USA; providing Gamma Irradiation services. Added product listing matrix to comply with new scope requirements.