

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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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 522460

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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

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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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List of Significant Subcontractors

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

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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

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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.

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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.