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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):

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:

STERIS Corporation
2720 Gunter Park Drive East
Montgomery
Alabama
36109
USA

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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EC Certificate - Production Quality Assurance

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**

Date: **2019-10-10**

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

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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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 522460**

Date: **2019-10-10**

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

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.

STERIS Corporation
2720 Gunter Park Drive East
Montgomery
Alabama
36109
United States

16 February 2024

Notified Body Confirmation Letter

Reference: EU2023-607/788073

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

STERIS Corporation
2720 Gunter Park Drive East
Montgomery
Alabama
36109
United States

SRN Number: US-MF-000017676

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR

application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sterile Light Handle Cover	Class I device placed on the market in sterile condition	N/A	Certificate CE 522460 Expiry date: 2024-05-26 NB2797
Sterile Camera Handle Cover	Class I device placed on the market in sterile condition	N/A	Certificate CE 522460 Expiry date: 2024-05-26 NB2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/02/16	Initial issue