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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 01530**

Issued To: **STERIS Corporation**
5960 Heisley Road
Mentor
Ohio
44060
USA

In respect of:

The design and manufacture of sterile processing equipment, infection prevention systems and sterilant and disinfectant chemical products for use with equipment for the sterilization and/or high level disinfection of medical devices.

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):

Albert Roossien, Regulatory Lead

First Issued: **1997-01-20** Date: **2019-01-04** Expiry Date: **2023-07-10**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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

Certificate No: **CE 01530**

Date: **2019-01-04**

Issued To: **STERIS Corporation**
5960 Heisley Road
Mentor
Ohio
44060
USA

Subcontractor:	**Service(s) supplied**
Corporation STERIS Canada (also operating as STERIS Canada ULC) 490 Boulevard Armand-Paris Québec G1C 8A3 Canada	**Manufacture**
STERIS Corporation 6100 Heisley Road Mentor Ohio 44060 USA	**Manufacture**
STERIS Corporation St. Louis Operations 7501 Page Ave St.Louis Missouri 63133 USA	**Design** **Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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

Certificate No: **CE 01530**

Date: **2019-01-04**

Issued To: **STERIS Corporation**
5960 Heisley Road
Mentor
Ohio
44060
USA

Subcontractor:	Service(s) supplied
STERIS Finn-Aqua Teollisuustie 2 Tuusula 04300 Finland	**Manufacture**
STERIS Ireland Limited IDA Business & Technology Park Tullamore Co. Offaly R35 X865 Ireland	**EU Representative**
STERIS MEXICO, S.de R.L.de C.V. Avenida Avante 790 Parque Industrial Guadalupe Guadalupe Nuevo León 67190 Mexico	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01530**

Date: **2019-01-04**

Issued To: **STERIS Corporation**
5960 Heisley Road
Mentor
Ohio
44060
USA

Date	Reference Number	Action
20 January 1997		First Issue
09 July 2003		5 year renewal and addition of UK site for EU Regulatory activities (Vigilance).
16 March 2006		Scope clarification and the addition of disinfectants.
11 July 2008	7236989	Certificate renewal and additional sub-contractor 'STERIS MEXICO'
28 September 2012	7905781	Replacement of EU Representative with STERIS Ltd., Leicester, UK
16 May 2013	7944025	Certificate renewal.
10 April 2015	8286661	Addition of Steris Canada Corporation and another STERIS Corporation location in Mentor, Ohio (6100 Heisley Road) as significant subcontractors for manufacture.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01530**

Date: **2019-01-04**

Issued To: **STERIS Corporation**
5960 Heisley Road
Mentor
Ohio
44060
USA

Date	Reference Number	Action
01 May 2018	8746154	Addition of STERIS Finn-Aqua, Tusula, Finland as significant subcontractor for Manufacture. Change of EU Representative. From STERIS Ltd to STERIS Ireland Limited. Remove STERIS Corporation, Pinecone Drive, Mentor, Ohio from Significant Sub-contractor list. Remove STERIS Corporation, 6515 Hopkins Road, Mentor, Ohio from Significant Sub-contractor list. Addition of STERIS Corporation, St Louis Operations, , St. Louis, Missouri as Significant sub-contractor for design and manufacture.
3 July 2018	8897981	Certificate Renewal Amendment to subcontractor Steris Canada Corporation details to include "also operating as STERIS Canada ULC".
Current	7781671	Traceable to NB 0086.

STERIS Corporation
5960 Heisley Road
Mentor
Ohio
44060
USA

11 August 2023

Notified Body Confirmation Letter

Reference: EU2023-607/671105

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
5960 Heisley Road
Mentor
Ohio
44060
USA

SRN Number: US-MF-000016007

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.,

Alan Till

Digitally signed by Alan Till
Date: 2023.08.11 14:51:25 +01'00'

Alan Till

BSI Scheme Manager

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
Enspire 3000 Cleaning & Liquid Chemical Sterilant Processing System	Class IIa	SYSTEM 1 Express Sterile Processing System	EC certificate # 01530 Expiry date 2023-07-10 NB # 2797
V-PRO s2 & V-PRO max 2 Low Temperature Processing System	Class IIa	Not Applicable	EC certificate # 01530 Expiry date 2023-07-10 NB # 2797
Revital-Ox Resert XL High Level Disinfectant	Class IIb – non implantable	Not Applicable	EC certificate # 01530 Expiry date 2023-07-10 NB # 2797
Vaprox HC Sterilant	Class IIa	Not Applicable	EC certificate # 01530 Expiry date 2023-07-10 NB # 2797
Reliance HLD High Level Disinfectant (for use in Reliance EPS Endoscope Processing System)	Class IIb – non implantable	Not Applicable	EC certificate # 01530 Expiry date 2023-07-10 NB # 2797
AMSCO 600 Steam Sterilizer	Class IIa	Not Applicable	EC certificate # 01530 Expiry date 2023-07-10 NB # 2797
AMSCO 300 Steam Sterilizer	Class IIa	Not Applicable	EC certificate # 01530 Expiry date 2023-07-10 NB # 2797
S40 Sterilant Concentrate	Class IIa	Not Applicable	EC certificate # 01530 Expiry date 2023-07-10 NB # 2797

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
2023/08/11	Initial issue

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Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	STERIS Corporation
Manufacturer address and contact details	5960 Heisley Road, Mentor, Ohio, 44060, USA
Single Registration Number (SRN) (if available)	US-MF-000016007

Authorised Representative name (if applicable)	STERIS Ireland Limited
Authorised Representative address and contact details	IDA Business & Technology Park, Tullamore, Co. Offaly, R35 X865, Ireland
Single Registration Number (SRN) (if available)	IE-AR-000010065

Notified body name (if applicable)	□ See attached schedule
Notified body number (if applicable)	□ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	□ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	□ See attached schedule
End date of extended validity/transition period	□ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

5960 Heisley Road, Mentor, Ohio 44060, USA www.steris.com

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☒ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: STERIS Corporation

Date: Aug 1, 2023

Signature:

Print Name: James Shearn

Title: Director, Regulatory Affairs & Quality Compliance

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
SYSTEM 1 Express Sterile Processing System	CE 01530	2023-07-10	BSI – British Standards Institution - 2797	2028-12-31	Enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System
V-PRO s2 & V-PRO max 2 Low Temperature Processing System	CE 01530	2023-07-10	BSI – British Standards Institution - 2797	2028-12-31	n/a
V-PRO 60 Low Temperature Processing System	CE 01530	2023-07-10	BSI – British Standards Institution - 2797	2028-12-31*	n/a
AMSCO 600 Steam Steriliser	CE 01530	2023-07-10	BSI – British Standards Institution - 2797	2028-12-31	n/a
AMSCO 300 Steam Steriliser	CE 01530	2023-07-10	BSI – British Standards Institution - 2797	2028-12-31	n/a
STERIS Amsco Evolution Medium Steam Sterilizer	CE 01530	2023-07-10	BSI – British Standards Institution - 2797	2028-12-31*	n/a
Revital-Ox Resert XL High Level Disinfectant	CE 01530	2023-07-10	BSI – British Standards Institution - 2797	2028-12-31	n/a
STERIS 20 Sterilant Concentrate (for use with obsolete System 1 sterilizer	CE 01530	2023-07-10	BSI – British Standards Institution - 2797	2028-12-31*	n/a
S40 Sterilant Concentrate	CE 01530	2023-07-10	BSI – British Standards Institution - 2797	2028-12-31	n/a
VAPROX HC Sterilant	CE 01530	2023-07-10	BSI – British Standards Institution - 2797	2028-12-31	n/a
Reliance HLD High Level Disinfectant (for use in Reliance EPS Endoscope Processing System)	CE 01530	2023-07-10	BSI – British Standards Institution - 2797	2028-12-31	n/a

*Subject to submission of application to the Notified Body prior to the 26th May 2024.

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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