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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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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List of Significant Subcontractors

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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**

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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.

bsi.

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Issued To: **STERIS Corporation**
5960 Heisley Road
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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.