EC Certificate - Full Quality Assurance System

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

No. **CE 501520**

Issued To: **Corporation STERIS Canada**
(also Operating as STERIS Canada ULC)
490 Boulevard Armand-Paris
Québec (Québec)
G1C 8A3
Canada

In respect of:

The design and manufacture of washer-disinfectors and sterile processing equipment for healthcare facilities.

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: **2005-11-02** Date: **2019-01-03** Expiry Date: **2023-07-19**

...making excellence a habit.™

By Royal Charter

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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**
STERIS Corporation 5960 Heisley Road Mentor Ohio 44060 USA	**Design**
STERIS Ireland Limited IDA Business & Technology Park Tullamore Co. Offaly R35 X865 Ireland	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
02 November 2005		First Issue. Transfer from TUV, certificate number G1 03 09 24353 002.
24 April 2007		Re-issue due to change of town in company address. Amendment of TUV Certificate number on history page.
10 September 2008	7161614	Certificate Renewal.
20 July 2013	8000916	Certificate Renewal. Addition of STERIS Ltd. as the EU Representative.
10 April 2015	8286662	Extension to scope to include sterile processing equipment, removal of accessories from scope and addition of ENDO-TECHNIK Wolfgang Griesat GmbH as a significant subcontractor for design and manufacture.
23 January 2016	8455721	Certificate reissue due to legal manufacturer name change from Steris Canada Corporation to Corporation STERIS Canada, 490 Boulevard Armand-Paris, Québec (Québec), CANADA G1C 8A3.

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Date	Reference Number	Action
03 July 2018	8897989	Certificate Renewal. Change EU Representative to Steris Ireland Limited. Remove significant sub-contractor ENDO-TECHNIK Wolfgang Griesat GmbH. Add significant sub-contractor Steris Corporation, 5960 Heisley Road, Mentor, OH for design. Amend main address details to include "also operating as STERIS Canada ULC".
Current	8935067	Traceable to NB 0086.