EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 759763 R000

Manufacturer: STERIS Corporation

Address:
5960 Heisley Road
Mentor
Ohio
44060
USA

Single Registration Number: US-MF-000016007

EU Authorised Representative: STERIS Ireland Limited

Address:
IDA Business & Technology Park
Tullamore
Co. Offaly
R35 X865
Ireland

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-03-28**

Current Issue Date: **2023-08-25**

Starting Validity Date: **2023-08-25**

Expiry Date: **2028-03-27**

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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
D050103 - Peracetic acid and associates for the disinfection of medical devices	Intended to provide high level disinfection or sterilization of medical devices at the end point of processing
D0502 - Hydrogen Peroxide for disinfection of medical devices	Intended to provide high level disinfection or sterilization of medical devices at the end point of processing

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
MDA0317 - Active non-implantable devices for cleaning, disinfection and sterilisation	Class IIa
MDN1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-03-28	3558796	Issued
Current	30002463	Amended – Addition of subcontractor for manufacture of non-active non-implantable devices for disinfecting, cleaning and rinsing

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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