EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 789778 R000

Manufacturer: STERIS IMS Limited

Address:
14 Pindar Road
Hoddesdon
Hertfordshire
EN11 0BZ
United Kingdom

Single Registration Number: UK-MF-000042027

EU Authorised Representative: STERIS Ireland Limited

Address:
IDA Business and Technology Park
Tullamore
County 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 XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X 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 Global Regulatory & Quality

First Issue Date: **2024-06-25**

Current Issue Date: **2025-02-10**

Starting Validity Date: **2025-02-10**

Expiry Date: **2029-06-24**

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

Device(s)	Risk Classification
Sharp instruments, reusable	Class Ir
Suture instruments, reusable	Class Ir
General surgery instruments, reusable	Class Ir
Abdominal surgery instruments, reusable	Class Ir
Obstetrics and gynecology instruments, reusable	Class Ir
Cardiovascular surgery instruments, reusable	Class Ir
Thoracic surgery instruments, reusable	Class Ir
Orthopedic and traumatological surgery instruments, reusable	Class Ir
Neurosurgery and spinal surgery instruments, reusable	Class Ir
ENT instruments, reusable	Class Ir
Odontostomatology instruments, reusable	Class Ir
Ophthalmology instruments, reusable	Class Ir
Surgical instruments, reusable – other	Class Ir
For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.	

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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
2024-06-25	3912256	Issued
Current	30360302	Restricted – Removal of Urology instruments, reusable and Microsurgery instruments, reusable.

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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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