

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

STERIS IMS LIMITED 14 Pindar Road, Hoddesdon, Hertfordshire, EN11 0BZ, United Kingdom

has been assessed against the requirements of Annex II of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ 0957414/B

Original Approval: 21 August 1997

Current Certificate: 1 September 2018

Certificate Expiry: 31 August 2021

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited



EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM CERTIFICATE LRQ 0957414/B SCHEDULE

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

> STERIS IMS LIMITED 14 Pindar Road, Hoddesdon, Hertfordshire, EN11 0BZ, United Kingdom

Class IIb Products

Tracheostomy Tubes Monopolar and Bipolar Instruments

Schedule Issue:

01

Date of Schedule Issue:

1 September 2018

LRQA Notified Body Number 0088

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Page 1 of 1

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