

EC Certificate - Full Quality Assurance System

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

No. CE 704932
Issued To: **STERIS SAS**
116 Avenue de Magudas
Le Haillan
33185
France

In respect of:

Design and manufacture of equipment management systems for distribution of medical gases, distribution of low voltage electrical power, signal transmission and carrying medical equipment.

Conception et fabrication de systèmes de distribution pour la distribution de gaz médicaux, la distribution d'énergie basse tension, la transmission de signaux et le portage d'équipements médicaux.

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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-07-31**

Date: **2019-07-31**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 704932

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Number	Device sub-category	Intended purpose per IFU
Class IIb		
MD 1112	Equipment Management systems	Distribution of medical gases, distribution of low voltage electrical power, signal transmission and carrying medical equipment.

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Certificate History

Certificate No: **CE 704932**
Date: **2019-07-31**
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Certificate History

Date	Reference Number	Action
Current	9700004	First Issue – Transfer from another notified body

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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