

EC Certificate - Full Quality Assurance System

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

No. CE 710457
Issued To: **Eschmann Technologies Limited**
(Also Trading As Eschmann Equipment)
Eschmann House
15 Peter Road
Lancing
West Sussex
BN15 8TJ
United Kingdom

In respect of:

Design and manufacture of autoclaves for dental and surgical instruments, surgical suction units.

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: **2019-09-03**

Date: **2021-03-15**

Expiry Date: **2021-11-19**

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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.

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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Supplementary Information to CE 710457

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| NBOG code(s) | Device description | Intended purpose |
|---------------------|------------------------|---|
| Class IIb | | |
| MD 1107 MDS 7010 | Autoclaves | Intended for sterilisation of medical instruments |
| Class IIa | | |
| MD 1107 MDS 7010 | Surgical Suction Units | N/A – not required for class IIa devices |

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EC Certificate - Full Quality Assurance System Certificate History

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| Date | Reference Number | Action |
|-------------------|------------------|---|
| 03 September 2019 | 9759087 | Issue of the certificate following a legal entity change from Eschmann Holdings Ltd (Also Trading As Eschmann Equipment) to Eschmann Technologies Limited. Traceable to CE 678766. Reduction of scope. Addition of product table. |
| Current | 3219007 | Added surgical suction units under scope; subcontractor supplier of class IIa autoclaves removed; device table updated. |