

# EC Certificate - Full Quality Assurance System

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

**No.****CE 678766****Issued To:**

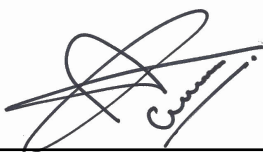
**Eschmann Holdings Ltd  
(Also Trading As Eschmann Equipment)  
Eschmann House, Lancing Business Park  
15 Peter Road  
Lancing  
West Sussex  
BN15 8TJ  
United Kingdom**

**In respect of:**

**Design and manufacture of autoclaves for dental and surgical instruments. Electro surgery units including reusable monopolar, bipolar and laparoscopic electrosurgical instruments, surgical suction units, patient plates and reusable finger switch for electro surgery.**

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):



Albert Roossien, Regulatory Lead

First Issued: **2017-11-07**

Date: **2019-01-11**

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.

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

## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 678766**  
 Date: **2019-01-11**  
 Issued To: **Eschmann Holdings Ltd**  
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**15 Peter Road**  
**Lancing**  
**West Sussex**  
**BN15 8TJ**  
**United Kingdom**

Subcontractor:	Service(s) supplied
Emed SP.ZO.O.SP.K Ryzowa 69a, Opacz-Kolonia 05-816 Poland	Finished Device Supplier
Gunter Bissinger Medizintechnik GmbH Hans-Theisen-Str. 1, Teningen, 79331 Germany	Finished Device Supplier
Leonhard Lang GmbH Archenweg 56 Innsbruck 6020 Austria	Finished Device Supplier

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### Subcontractor:

### Service(s) supplied

SciCan Ltd  
 1440 Don Mills Road,  
 Toronto,  
 Ontario  
 M3B 3P9  
 Canada

**Finished Device Supplier**

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## Certificate History

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Date	Reference Number	Action
07 November 2017	8783686	First Issue. Transfer from another notified body.
Current	8893350	Traceable to NB 0086.

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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.