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EC Certificate - Full Quality Assurance System

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

No. **CE 00482**

Issued To: **Swann-Morton Limited**
Owlerton Green
Sheffield
South Yorkshire
S6 2BJ
United Kingdom

In respect of:

The design and manufacture of sterile and non-sterile stainless steel and carbon steel surgical blades, scalpels and skin graft blades

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):

Digitally signed by Iarovoi Petru
Date: 2020.02.11 11:23:10 EET
Reason: MoldSign Signature
Location: Moldova

Albert Roossien, Regulatory Lead

First Issued: **1995-02-01** Date: **2019-02-08** Expiry Date: **2021-05-16**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 59550**

Issued To: **Swann-Morton Limited**
Owlerton Green
Sheffield
South Yorkshire
S6 2BJ
United Kingdom

In respect of:

Those aspects of Annex V related to securing and maintaining the sterility in the manufacture of sterile stitch cutters

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2001-07-12** Date: **2020-03-25** Expiry Date: **2021-05-16**

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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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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Swann-Morton Limited
Owlerton Green
Sheffield
S6 2BJ
United Kingdom

Holds Certificate No: **FM 73368**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, manufacture, packaging and distribution of surgical blades, disposable scalpels, handles and blade removers.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2002-12-24
Latest Revision Date: 2020-11-05

Effective Date: 2020-11-18
Expiry Date: 2023-11-17

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