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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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Digitally signed by Iarovoi Petru
Date: 2021.10.09 19:35:16 EEST
Reason: MoldSign Signature
Location: Moldova

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 721051 R000

Manufacturer: Swann-Morton Limited

Address:
Owlerton Green
Sheffield
S6 2BJ
United Kingdom

Single Registration Number: GB-MF-000001890

EU Authorised Representative: Emergo Europe

Address:
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-01-20** Date: **2021-11-23** Expiry Date: **2026-01-19**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 721051 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Single use surgical scalpels and blades	Class IIa
Sterile suture remover	Class Is
Reusable instruments 'Orthopaedic Instruments'	Class Ir

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

For class Ir devices (class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device

First Issued: **2021-01-20** Date: **2021-11-23** Expiry Date: **2026-01-19**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 721051 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
2021-01-20	3103832	Issued
Current	3539989	Supplemented - Addition of Class Ir devices Amended - Removal of subcontractor Woodland Works Amended – Addition of SRN code: GB-MF-000001890 Amended – Administrative update on activity for "gamma irradiation" to "Radiation (Gamma Sterilization)" for Swann-Morton (Services) Limited Penn Works and on history section for "First issue" to "Issued"

First Issued: **2021-01-20** Date: **2021-11-23** Expiry Date: **2026-01-19**

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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 721051 R000

Date: **2021-11-23**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Andersen Caledonia Limited Caledonian House Phoenix Crescent Strathclyde Business Park Lanarkshire ML4 3NJ United Kingdom	**ETO Sterilization**
Jewel Blade Ltd 442 Penistone Road Sheffield S6 2FU United Kingdom	**Crucial Supplier**
Swann-Morton (Microbiological Laboratory Services) Limited Owlerton Green Sheffield S6 2BJ United Kingdom	**Microbiology Service**
Swann-Morton (Services) Limited Penn Works Owlerton Green Sheffield S6 2BJ United Kingdom	**Radiation (Gamma Sterilization)**

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