

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

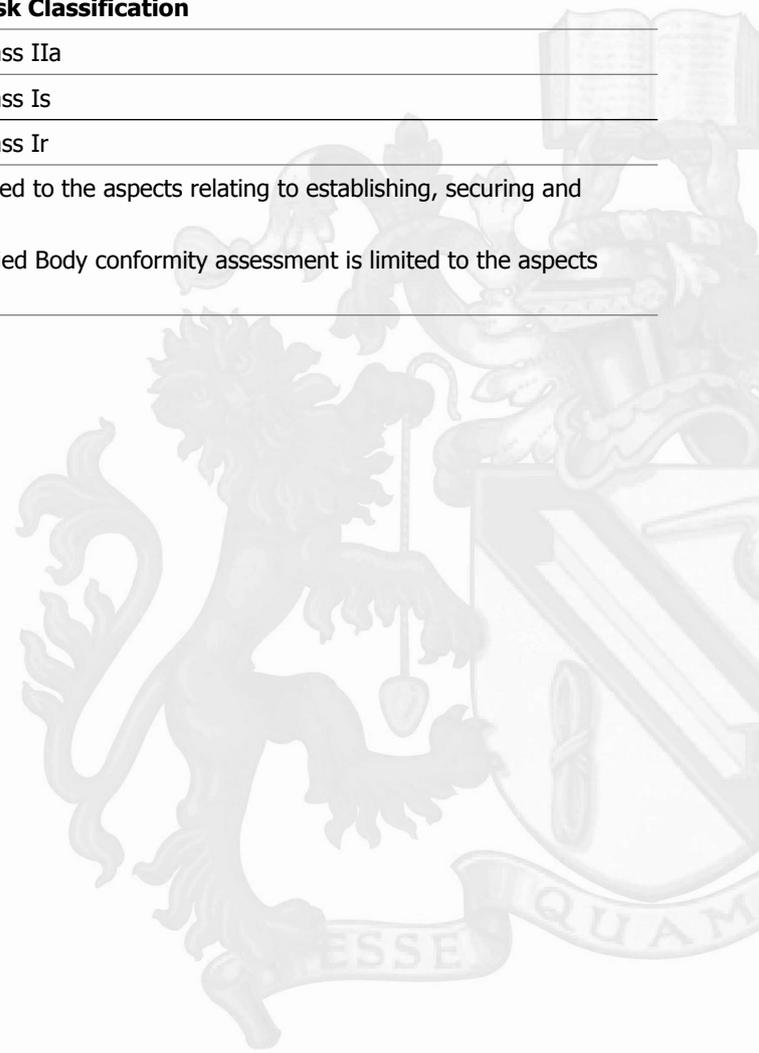
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Device Schedule: Class IIa, Custom-made and other devices

| 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



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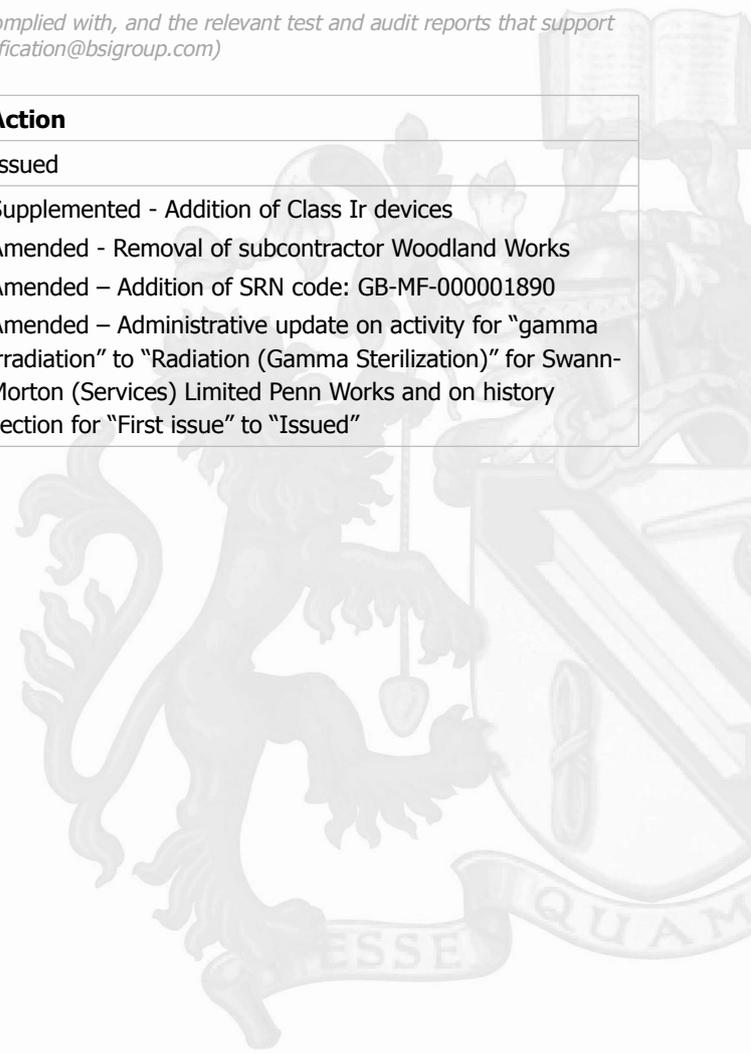
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Certificate History

(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” |



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Validity of this certificate is conditional on the Manufacturer’s quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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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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