By Royal Charter

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:
Westervoortsedijk 60
6827 AT Arnhem
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 devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-01-20**

Current Issue Date: **2024-03-22**

Starting Validity Date: **2024-03-22**

Expiry Date: **2026-01-19**

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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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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
2021-11-23	3539989	Supplemented - Addition of Class Ir devices Amended - Removal of subcontractor 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"
Current	30053564	Amended – Change EU Authorised Rep address to: Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands Amended – Removal of Subcontractor page.

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