

## Declaration of Conformity

**Manufacturer's Name:** Swann-Morton Limited  
**Manufacturer's Address:** Owlerton Green,  
Sheffield, S6 2BJ, England  
**Single Registration Number:** GB-MF-000001890  
**BUDI-DI** 50339550STERILEMYRINDQ

**European Authorised Representative Name:** Emergo Europe  
**European Authorised Representative Address:** Westervoortsedijk 60  
6827 AT Arnhem  
The Netherlands  
**Single Registration Number:** NL-AR-000000116

This Declaration of Conformity is issued under our sole responsibility as manufacturer of the devices covered by this declaration, Swann-Morton Limited, hereby ensure and declare that these devices meet the provisions of the medical devices regulations (EU) 2017/745.

The Notified Body used for our conformity assessment in accordance with Annex IV and Annex IX of the above Regulation is BSI NL (2797).

Certificates Issued:

**MDR 721051 R000** in respect of: Single use surgical scalpels and blades

**FM73368:** Operates a Quality Management System which complies with the requirements of ISO 13485 for the following scope: The design, manufacture, packaging and distribution of surgical blades, disposable scalpels, handles and blade removers.

**MDSAP 674417** – The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016, Australia – Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure, Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3 Part 4 – Production Quality Assurance Procedure; Brazil – RDC ANVISA n.665/2022, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada Medical Device Regulations – Part 1 – SOR 98/282; Japan – MHLW Ministerial Ordinance 169, Article 4 to 68, PMD Act AND USA – 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D. The design, manufacture, packaging and distribution of surgical blades, disposable scalpels, handles and blade removers.

**Country Registrations:**

Canada Medical Device License: 5606

U.S.A Establishment Registration & Device Listing (FDA) Registration No. 9611194 Owner/Operator No. 9003320.

Australian Register of Therapeutic Goods Certificate: 114374

Brazilian RDC number: 10302860224

Japan MHLW registration number: BG20500131

<b>Product Family:</b>	STERILE MYRINGOTOMY BLADES
<b>Intended Use:</b>	SKIN AND TISSUE CUTTING
<b>Product Codes:</b>	See Page 3
<b>Classification:</b>	Class IIa (Annex VIII, Rule 6) (EU) Class II (MDR Schedule 1, Part 1, Rule 1(1) (Health Canada) Class I (FDA CFR 878.4800) (U.S.A – FDA) Class IIa (TG(MD)R 2002) Schedule 3 Part 3.2(2) (Australia) Class II (RDC Annex II, II, 2. Rule 6) (Brazil) Class II (JMDN: 35130002 Rule 6) (Japan)
<b>Standards Used:</b>	See Table Below
<b>GMDN Code &amp; Term</b>	37445 Blade, Scalpel, Single Use A component of a surgical instrument (scalpel) that is designed to be attached to a handle. It is capable of cutting through tissue when moved with downward pressure.

Standards applied in relation to this Declaration are:

STANDARD NUMBER	TITLE
BS EN 556-1	Sterilization of medical devices – Requirements for medical devices to be designated “Sterile” – Part 1: Requirements for terminally sterilized medical devices
BS EN ISO 20417	Medical devices - Information to be supplied by the manufacturer
BS EN ISO 11607-1	Packaging of terminally sterilized medical devices. Part 1: Requirements for materials, sterile barrier systems & packaging systems
BS EN ISO 11607-2	Packaging of terminally sterilized medical devices. Part 2: Validation requirements for forming, sealing & assembly processes
BS EN ISO 10993-1	Biological evaluation of medical devices
BS EN ISO 11137-1	Sterilization of healthcare products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
BS EN ISO 11137-2	Sterilization of healthcare products – Radiation – Part 2: Establishing the sterilization dose
BS EN ISO 7153-1	Surgical instruments – Metallic materials – Specification for stainless steel
BS EN ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling & information to be supplied
BS EN ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
BS EN ISO 14971	Medical devices – Application of risk management to medical devices
BS EN ISO 16061	Instrumentation for use in association with non-active surgical instruments – General requirements

PRODUCT DESCRIPTION	PRODUCT CODE	UDI
Swann Morton Sterile Myringotomy Blades	2102	05033955021023

Signed for and on behalf of Swann-Morton Limited, Owlerton Green, Sheffield S6 2BJ

<b>SIGNATURE</b>	
<b>PRINT FULL NAME</b>	Darren Hall
<b>POSITION</b>	QA/RA Systems Manager
<b>PLACE &amp; DATE</b>	Swann-Morton Ltd, Sheffield S6 2BJ, England 1 <sup>st</sup> February 2023