Swann-Morton® LIMITED

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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	50339550STERILEFINE6U
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 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

VAT Reg No. GB 172 8625 45 Reg No. 696744 ENGLAND

Product Family:	STERILE FINE SURGICAL BLADES
Intended Use:	SKIN AND TISSUE CUTTING
Product Codes:	See Page 3
Classification:	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)
Standards Used:	See Table Below
GMDN Code & Term	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

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PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Swann Morton Sterile Fine Surgical Blade	SM61	5901	05033955059019
Swann Morton Sterile Fine Surgical Blade	SM62	5902	05033955059026
Swann Morton Sterile Fine Surgical Blade	SM63	5903	05033955059033
Swann Morton Sterile Fine Surgical Blade	SM64	5904	05033955059040
Swann Morton Sterile Fine Surgical Blade	SM65	5905	05033955059057
Swann Morton Sterile Fine Surgical Blade	SM65A	5906	05033955059064
Swann Morton Sterile Fine Surgical Blade	SM67	5907	05033955059071
Swann Morton Sterile Fine Surgical Blade	SM68	5908	05033955059088
Swann Morton Sterile Fine Surgical Blade	SM69	5909	05033955059095
Swann Morton Sterile Fine Surgical Blade	Single Bevel Fine SM61	5911	05033955059118
Swann Morton Sterile Fine Surgical Blade	Single Bevel Fine SM62	5912	05033955059125
Swann Morton Sterile Fine Surgical Blade	Fine 90 (SP)	5921	05033955059217
Swann Morton Sterile Fine Surgical Blade	Fine 91 (SP)	5922	05033955059224

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

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

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