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	50339550STERILESKGRAFTRT
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: 297237
Brazilian RDC number: 10302860262
Japan MHLW registration number: BG20500131

Digitally signed by
Date: 2024.04.02 1
Reason: MoldSign
Location: Moldova

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

Product Family:	STERILE SKIN GRAFT BLADES
Intended Use:	SKIN AND TISSUE CUTTING SKIN AND TISSUE SLICING/LIFTING PORTIONS OF DERMIS FOR SKIN GRAFTING OPERATIONS
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 Below
GMDN Code & Term	35134 Blade, Dermatome, Single Use. To fit a dermatome. A surgical instrument used for harvesting skin for grafting purposes.

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

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PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Swann-Morton Sterile Skin Graft Blades	SG3	2201	05033955022013
Swann-Morton Sterile Skin Graft Blades	SGD	2203	05033955022037
Swann-Morton Sterile Skin Graft Blades (158mm)	N/A	9940	05033955099404
Swann-Morton Sterile Skin Graft Blades (Silvers)	N/A	9942	05033955099428
Swann-Morton Sterile Skin Graft Blade DER 001	N/A	9943	05033955099435
Swann-Morton Sterile Skin Graft Blades DER 002	N/A	9944	05033955099442
Swann-Morton Sterile Skin Graft Blades DER 003	N/A	9945	05033955099459
Paragon Sterile Skin Graft Blades (158mm)	N/A	PS50	05033955120504
Swann-Morton Sterile Skin Graft Blades + Non-Sterile Braithwaite Handle	N/A	9904	05033955099046
Swann-Morton Sterile Skin Graft Blades + Non-Sterile Cobbett Handle	N/A	9905	05033955099053
Swann-Morton Sterile Skin Graft Blades + Non-Sterile Watson Handle	N/A	9906	05033955099060

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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