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	50339550NONSTPDHANDLEGU
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:

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: 72
U.S.A Establishment Registration & Device Listing (FDA) Registration No. 9611194 Owner/Operator No. 9003320.
Australian Register of Therapeutic Goods Certificate: 107772
Brazilian RDC number: N/A
Japan MHLW registration number: BG20500131

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

Product Family:	NON-STERILE PD HANDLES
Intended Use:	TO HOLD A PD SURGICAL BLADE
Product Codes:	See Table Below
Classification:	Class I (Reusable) (Annex VIII, Rule 6) (EU) Class I (MDR Schedule 1, Part 1, Rule 3 (Health Canada) Class I (FDA CFR 878.4800) (U.S.A – FDA) Class I (TG(MD)R 2002) Schedule 2 Part 3.2(4) (Australia) Class I (RDC Annex II, II, 1. Rule 1) (Brazil) Class I (JMDN: 12235000 Rule 6) (Japan)
Standards Used:	See Table Below
GMDN Code & Term	12235 Knife/Blade Handle A metal surgical instrument, e.g. stainless steel or brass, designed to mount a compatible blade used for cutting or dissecting tissue.

Standards applied in relation to this Declaration are:

STANDARD NUMBER	TITLE
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 17664 – 1	Processing of healthcare products, information to be provided by the medical device manufacturer for the processing of medical devices
BS EN ISO 20417	Medical Devices – Information to be supplied by the manufacturer

PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Swann-Morton Non-Sterile PD Handle	N/A	5810	05033955058104

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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