

## Declaration of Conformity

<b>Manufacturer's Name:</b>	Swann-Morton Limited
<b>Manufacturer's Address:</b>	Owlerton Green, Sheffield, S6 2BJ, England
<b>Single Registration Number:</b>	GB-MF-000001890
<b>BUDI-DI</b>	50339550NONSTFINEHANDLE4K
<b>European Authorised Representative Name:</b>	Emergo Europe
<b>European Authorised Representative Address:</b>	Westervoortsedijk 60 6827 AT Arnhem The Netherlands
<b>Single Registration Number:</b>	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: Reusable Instruments

For Class 1r devices (class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.

**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: 10302860262

Japan MHLW registration number: BG20500131


<b>Product Family:</b>	NON-STERILE FINE HANDLES
<b>Intended Use:</b>	TO HOLD A FINE SURGICAL BLADE
<b>Product Codes:</b>	See Table Below
<b>Classification:</b>	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)
<b>Standards Used:</b>	See Table Below
<b>GMDN Code &amp; Term</b>	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 Fine Handle	SF1	6051	05033955060510
Swann-Morton Non-Sterile Fine Handle	SF2	6052	05033955060527
Swann-Morton Non-Sterile Fine Handle	SF3	6053	05033955060534
Swann-Morton Non-Sterile Fine Handle	SF4	6054	05033955060541
Swann-Morton Non-Sterile Fine Handle	2 Piece long	6055	05033955060558
Swann-Morton Non-Sterile Fine Handle	3 Piece long	6056	05033955060565
Swann-Morton Non-Sterile Fine Handle	SF13	6061	05033955060619
Swann-Morton Non-Sterile Fine Handle	SF23	6062	05033955060626

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 11 <sup>th</sup> May 2023