

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	50339550NSTMINORDISPSS7
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: 104897

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

Australian Register of Therapeutic Goods Certificate: N/A

Brazilian RDC number: 10302860213

Japan MHLW registration number: BG20500131


Product Family:	NON-STERILE MINOR DISPOSABLE SCALPELS
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	47569: Scalpel, Single Use A hand held, manual surgical instrument constructed as a one-piece handle and scalpel blade (not an exchangeable component) used by the operator to manually cut or dissect tissue. The blade is typically made of high-grade stainless steel alloy or carbon steel and the handle is often made of plastic. This is a single use device.

Standards applied in relation to this Declaration are:

STANDARD NUMBER	TITLE
BS EN ISO 10993-1	Biological evaluation of medical devices
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
BS EN ISO 20417	Medical devices - Information to be supplied by the manufacturer

PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Box of 100			
Swann-Morton Non-Sterile Minor Disposable Scalpels	10	2371	05033955023713
Swann-Morton Non-Sterile Minor Disposable Scalpels	10A	2372	05033955023720
Swann-Morton Non-Sterile Minor Disposable Scalpels	11	2373	05033955023737
Swann-Morton Non-Sterile Minor Disposable Scalpels	15	2375	05033955023751
Swann-Morton Non-Sterile Minor Disposable Scalpels	15A	2376	05033955023768
Per 10			
Swann-Morton Non-Sterile Minor Disposable Scalpels	10	2381	05033955023812
Swann-Morton Non-Sterile Minor Disposable Scalpels	10A	2382	05033955023829
Swann-Morton Non-Sterile Minor Disposable Scalpels	11	2383	05033955023836
Swann-Morton Non-Sterile Minor Disposable Scalpels	15	2385	05033955023850
Swann-Morton Non-Sterile Minor Disposable Scalpels	15A	2386	05033955023867
Swann-Morton Non-Sterile Minor Disposable Scalpels	15C	2387	05033955023874

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 5 th July 2023

