

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 50339550NONSTDISPSH9
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

*disposable
scalpels
non-sterile
(202)*

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: 114372

Brazilian RDC number: 10302860213

Japan MHLW registration number: BG20500131

Product Family:	NON-STERILE DISPOSABLE SCALPELS
Intended Use:	SKIN AND TISSUE CUTTING
Product Codes:	See Page 3 and 4
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 requirements
BS EN ISO 20417	Medical devices - Information to be supplied by the manufacturer

PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Swann-Morton Non-Sterile Disposable Scalpels w/ guards	10	2331	05033955023317
Swann-Morton Non-Sterile Disposable Scalpels w/ guards	10A	2332	05033955023324
Swann-Morton Non-Sterile Disposable Scalpels w/ guards	11	2333	05033955023331
Swann-Morton Non-Sterile Disposable Scalpels w/ guards	11 P	2391	05033955023911
Swann-Morton Non-Sterile Disposable Scalpels w/ guards	12	2334	05033955023348
Swann-Morton Non-Sterile Disposable Scalpels w/ guards	15	2335	05033955023355
Swann-Morton Non-Sterile Disposable Scalpels w/ guards	20	2336	05033955023362
Swann-Morton Non-Sterile Disposable Scalpels w/ guards	21	2341	05033955023416
Swann-Morton Non-Sterile Disposable Scalpels w/ guards	22	2342	05033955023423
Swann-Morton Non-Sterile Disposable Scalpels w/ guards	23	2337	05033955023379
Swann-Morton Non-Sterile Disposable Scalpels w/ guards	24	2339	05033955023393
Swann-Morton Non-Sterile Disposable Scalpels w/ guards	25A	2338	05033955023386
Swann-Morton Non-Sterile Disposable Scalpels w/ guards	26	2346	05033955023461
Swann-Morton Non-Sterile Disposable Scalpels w/ guards	19	2352	05033955023522

PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Swann-Morton Non-Sterile Retractable Scalpels	10	4001	05033955040017
Swann-Morton Non-Sterile Retractable Scalpels	10A	4002	05033955040024
Swann-Morton Non-Sterile Retractable Scalpels	11P	4091	05033955040918
Swann-Morton Non-Sterile Retractable Scalpels	12	4004	05033955040048
Swann-Morton Non-Sterile Retractable Scalpels	15	4005	05033955040055
Swann-Morton Non-Sterile Retractable Scalpels	20	4006	05033955040062
Swann-Morton Non-Sterile Retractable Scalpels	21	4007	05033955040079
Swann-Morton Non-Sterile Retractable Scalpels	22	4008	05033955040086
Swann-Morton Non-Sterile Retractable Scalpels	23	4010	05033955040109
Swann-Morton Non-Sterile Retractable Scalpels	24	4011	05033955040116
Swann-Morton Non-Sterile Retractable Scalpels	25A	4015	05033955040154
Swann-Morton Non-Sterile Retractable Scalpels	14	4019	05033955040192
Swann-Morton Non-Sterile Retractable Scalpels	15C	4021	05033955040215
Swann-Morton Non-Sterile Retractable Scalpels	10R	4090	05033955040901


PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Lance Non-Sterile Disposable Scalpel	11	LC03	05033955160036
Lance Non-Sterile Disposable Scalpel	15T	LC92	05033955160920
Lance Non-Sterile Disposable Scalpel (For Becton Dickinson Only)	11	LC23	05033955160234

PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Paragon Non-Sterile Disposable Scalpel	10	PC01	05033955140014
Paragon Non-Sterile Disposable Scalpel	11	PC03	05033955140038
Paragon Non-Sterile Disposable Scalpel	12	PC04	05033955140045
Paragon Non-Sterile Disposable Scalpel	23	PC10	05033955140106

PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Paragon Non-Sterile Disposable Scalpel (For Smiths Only)	10	PC21	05033955140212
Paragon Non-Sterile Disposable Scalpel (For Smiths Only)	11	PC23	05033955140236
Paragon Non-Sterile Disposable Scalpel (For Smiths Only)	15	PC25	05033955140250

PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Neutral Non-Sterile Disposable Scalpel	11	NU03	05033955130039

Signed for and on behalf of Swann-Morton Limited at 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