

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	50339550STERILEEORET8S
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 ISO 13485:2016 including the following country specific requirements:

Australia – Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure;

Brazil – RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 – Good Manufacturing Practices, RDC ANVISA n. 551/2021;

Canada – Medical Device Regulations – Part 1 – SOR 98/282;

Japan – MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act;

USA – 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D.

The design, manufacture, 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: 114372

Brazilian RDC number: 10302860224

Japan MHLW registration number: BG20500131

Product Family:	STERILE EO RETRACTABLE 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 sterile, 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 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: Evaluation & Testing
BS EN ISO 10993-7	Biological evaluation of medical devices: Ethylene oxide sterilization residuals
BS EN ISO 11135	Sterilization of healthcare products – Ethylene Oxide - Requirements for development, validation and routine control of a sterilization process for 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

PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Swann-Morton Sterile Retractable Scalpels (25's)	10	3901	05033955039011
Swann-Morton Sterile Retractable Scalpels (25's)	15	3905	05033955039059
Swann-Morton Sterile Retractable Scalpels (25's)	20	3906	05033955039066
Swann-Morton Sterile Retractable Scalpels (25's)	21	3907	05033955039073
Swann-Morton Sterile Retractable Scalpels (25's)	22	3908	05033955039080
Swann-Morton Sterile Retractable Scalpels (25's)	23	3910	05033955039103
Swann-Morton Sterile Retractable Scalpels (25's)	24	3911	05033955039110
Swann-Morton Sterile Retractable Scalpels (25's)	25A	3915	05033955039158
Swann-Morton Sterile Retractable Scalpels (25's)	11P	3991	05033955039912
Swann-Morton Sterile Retractable Scalpels (25's)	10A	3902	05033955039028
Swann-Morton Sterile Retractable Scalpels (25's)	10R	3990	05033955039905
Swann-Morton Sterile Retractable Scalpels (25's)	12	3904	05033955039042
Swann-Morton Sterile Retractable Scalpels (25's)	14	3919	05033955039196
Swann-Morton Sterile Retractable Scalpels (25's)	15C	3921	05033955039219

PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Swann-Morton Sterile Retractable Scalpels (10's)	10	4901	05033955049010
Swann-Morton Sterile Retractable Scalpels (10's)	10A	4902	05033955049027
Swann-Morton Sterile Retractable Scalpels (10's)	12	4904	05033955049041
Swann-Morton Sterile Retractable Scalpels (10's)	15	4905	05033955049058
Swann-Morton Sterile Retractable Scalpels (10's)	20	4906	05033955049065
Swann-Morton Sterile Retractable Scalpels (10's)	21	4907	05033955049072
Swann-Morton Sterile Retractable Scalpels (10's)	22	4908	05033955049089
Swann-Morton Sterile Retractable Scalpels (10's)	23	4910	05033955049102
Swann-Morton Sterile Retractable Scalpels (10's)	24	4911	05033955049119
Swann-Morton Sterile Retractable Scalpels (10's)	25A	4915	05033955049157
Swann-Morton Sterile Retractable Scalpels (10's)	14	4919	05033955049195
Swann-Morton Sterile Retractable Scalpels (10's)	15C	4921	05033955049218
Swann-Morton Sterile Retractable Scalpels (10's)	10R	4990	05033955049904
Swann-Morton Sterile Retractable Scalpels (10's)	11P	4991	05033955049911

PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Swann-Morton Sterile Disposable Scalpel w/ Retracting Guard	10	3601	05033955036010
Swann-Morton Sterile Disposable Scalpel w/ Retracting Guard	11	3603	05033955036034
Swann-Morton Sterile Disposable Scalpel w/ Retracting Guard	12	3604	05033955036041
Swann-Morton Sterile Disposable Scalpel w/ Retracting Guard	15	3605	05033955036058
Swann-Morton Sterile Disposable Scalpel w/ Retracting Guard	20	3606	05033955036065
Swann-Morton Sterile Disposable Scalpel w/ Retracting Guard	21	3607	05033955036072
Swann-Morton Sterile Disposable Scalpel w/ Retracting Guard	22	3608	05033955036089
Swann-Morton Sterile Disposable Scalpel w/ Retracting Guard	23	3610	05033955036102
Swann-Morton Sterile Disposable Scalpel w/ Retracting Guard	24	3611	05033955036119
Swann-Morton Sterile Disposable Scalpel w/ Retracting Guard	11P	3691	05033955036911

PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Paragon Sterile Disposable Scalpel w/ Retracting Guard	10	P601	05033955106010
Paragon Sterile Disposable Scalpel w/ Retracting Guard	11	P603	05033955106034
Paragon Sterile Disposable Scalpel w/ Retracting Guard	15	P605	05033955106058
Paragon Sterile Disposable Scalpel w/ Retracting Guard	20	P606	05033955106065
Paragon Sterile Disposable Scalpel w/ Retracting Guard	21	P607	05033955106072
Paragon Sterile Disposable Scalpel w/ Retracting Guard	22	P608	05033955106089
Paragon Sterile Disposable Scalpel w/ Retracting Guard	23	P610	05033955106102
Paragon Sterile Disposable Scalpel w/ Retracting Guard	24	P611	05033955106119

Signed for and on behalf of Swann-Morton Limited, Owlerton Green, Sheffield S6 2BJ.

SIGNATURE	
PRINT FULL NAME	Rebecca Taylor
POSITION	QA/RA Systems Assistant Manager
PLACE & DATE	Swann-Morton Ltd, Sheffield S6 2BJ, England 20th December 2024