

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	50339550NONSTBLADES6V
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: 104897

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

Australian Register of Therapeutic Goods Certificate: 114374

Brazilian RDC number: 10302860213

Japan MHLW registration number: BG20500131

Product Family:	NON-STERILE SURGICAL BLADES
Intended Use:	SKIN AND TISSUE CUTTING
Product Codes:	See Pages 3, 4 & 5
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	37445 Blade, Scalpel, Single Use A component of a surgical instrument (scalpel) that is designed to be attached to a handle. It is capable of cutting through tissue when moved with downward pressure.

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 27740/ISO 7740	Instruments for surgery, scalpels with detachable blades
BS 2982	Materials and packaging of surgical scalpels with detachable blades
BS EN ISO 20417	Medical devices - Information to be supplied by the manufacturer
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	BLADE SHAPE	PRODUCT CODE	UDI
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	10	0101	05033955001018
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	10A	0102	05033955001025
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	11	0103	05033955001032
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	12	0104	05033955001049
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	15	0105	05033955001056
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	20	0106	05033955001063
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	21	0107	05033955001070
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	22	0108	05033955001087
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	22A	0109	05033955001094
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	23	0110	05033955001100
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	24	0111	05033955001117
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	25	0112	05033955001124
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	26	0113	05033955001131
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	27	0114	05033955001148
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	25A	0115	05033955001155
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	6	0116	05033955001162
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	9	0117	05033955001179
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	12D	0118	05033955001186
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	14	0119	05033955001193
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	15A	0120	05033955001209
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	15C	0121	05033955001216
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	16	0122	05033955001223
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	18	0123	05033955001230
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	19	0124	05033955001247
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	E11	0125	05033955001254
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	Sabre E/11	0183	05033955001834
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	Sabre D15	0185	05033955001858
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	Sabre B23	0190	05033955001902
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	11P	0191	05033955001919
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	15T	0192	05033955001926

PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	10	3001	05033955030018
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	10A	3002	05033955030025
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	11	3003	05033955030032
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	15	3005	05033955030056
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	21	3007	05033955030070
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	22	3008	05033955030087
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	22A	3009	05033955030094
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	23	3010	05033955030100
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	24	3011	05033955030117
Swann-Morton Non-Sterile Carbon Steel Surgical Blade	11P	3091	05033955030919

PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Swann-Morton Non-Sterile Stainless Steel Surgical Blade	Bulk No. 10	1901	05033955019013
Swann-Morton Non-Sterile Stainless Steel Surgical Blade	Bulk No. 15C	1902	05033955019020
Swann-Morton Non-Sterile Stainless Steel Surgical Blade	Bulk No. 12	1903	05033955019037
Swann-Morton Non-Sterile Stainless Steel Surgical Blade	Bulk No. 10A	1922	05033955019228
Swann-Morton Non-Sterile Stainless Steel Surgical Blade	Bulk No. 11	1923	05033955019235
Swann-Morton Non-Sterile Stainless Steel Surgical Blade	Bulk No. 11P	1910	05033955019105
Swann-Morton Non-Sterile Stainless Steel Surgical Blade	Bulk No. 20	1927	05033955019273
Swann-Morton Non-Sterile Stainless Steel Surgical Blade	Bulk No. 15T	1929	05033955019297
Swann-Morton Non-Sterile Stainless Steel Surgical Blade	Bulk No. 22	1930	05033955019303
Swann-Morton Non-Sterile Stainless Steel Surgical Blade	Bulk No. 23	1931	05033955019310
Swann-Morton Non-Sterile Stainless Steel Surgical Blade	Bulk No. 15	1940	05033955019402

PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
CMI Bulk No. 10 Stainless Steel Blades (BRAND)	Bulk No. 10	1962	05033955019624
CMI Bulk No. 11P Stainless Steel Blades (BRAND)	Bulk No. 11P	1963	05033955019631
CMI Bulk No. 15 Stainless Steel Blades (BRAND)	Bulk No. 15	1964	05033955019648
CMI Bulk No. 10A Stainless Steel Blades (BRAND)	Bulk No. 10A	1966	05033955019662
CMI Bulk No. E11 Stainless Steel Blades (BRAND)	Bulk No. E11	1967	05033955019679
CMI Bulk No. 15A Stainless Steel Blades (BRAND)	Bulk No. 15A	1969	05033955019693
CMI Bulk No. 15C Stainless Steel Blades (BRAND)	Bulk No. 15C	1970	05033955019709
CMI Bulk No. 20 Stainless Steel Blades (BRAND)	Bulk No. 20	1980	05033955019808
CMI Bulk No. 21 Stainless Steel Blades (BRAND)	Bulk No. 21	1981	05033955019815
CMI Bulk No. 22 Stainless Steel Blades (BRAND)	Bulk No. 22	1982	05033955019822
CMI Bulk No. 23 Stainless Steel Blades (BRAND)	Bulk No. 23	1983	05033955019839
CMI Bulk No. 24 Stainless Steel Blades (BRAND)	Bulk No. 24	1984	05033955019846
CMI Bulk No. 25A Stainless Steel Blades (BRAND)	Bulk No. 25A	1985	05033955019853

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

SIGNATURE	
PRINT FULL NAME	Darren Hall / Sally Shield
POSITION	QA/RA Systems Manager / QA/RA Assistant
PLACE & DATE	Swann-Morton Ltd, Sheffield S6 2BJ, England 15th November 2023

