

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Swann-Morton Limited
Owlerton Green
Sheffield
S6 2BJ
United Kingdom

Facility ID Number: F000431

Holds Certificate No: **MDSAP 674417**

The company listed on this certificate has been audited to and found to conform with 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 Devices 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.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2018-08-30

Effective Date: 2023-11-18

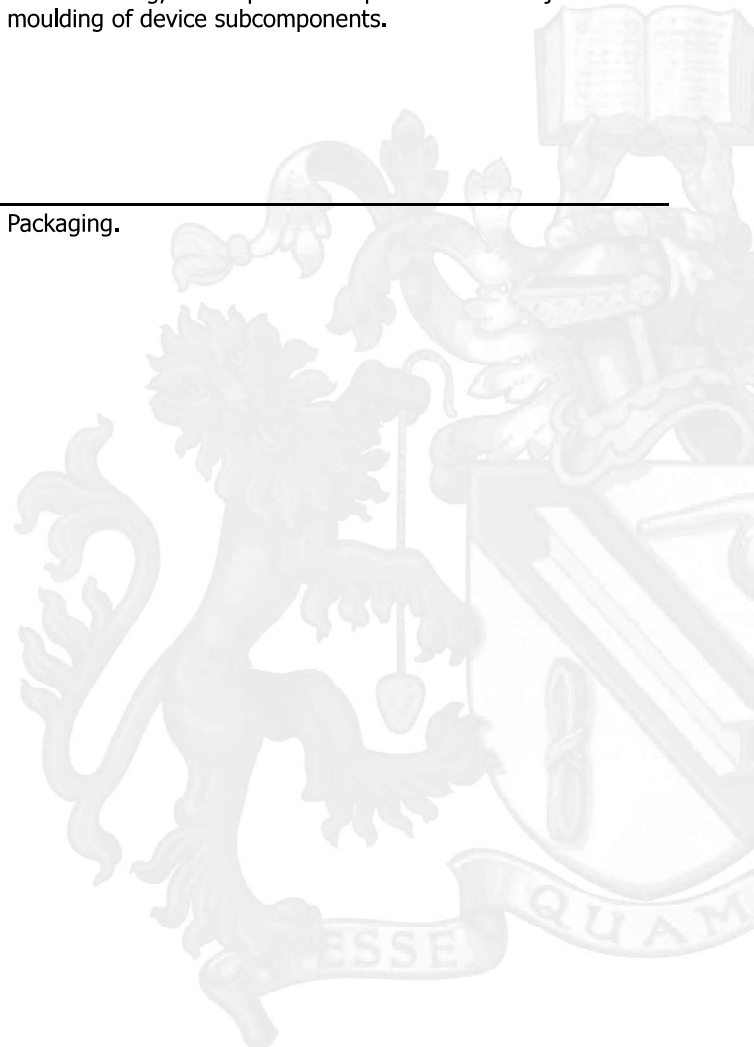
Expiry Date: 2026-11-17



BSI Group America Inc. is an MDSAP recognised auditing organization

Certificate No: **MDSAP 674417**

Location	Registered Activities
Swann-Morton Limited Owlerton Green Sheffield S6 2BJ United Kingdom Facility ID Number: F000431	The design, manufacture, packaging and distribution of surgical blades, disposable scalpels, handles and blade removers.
Swann-Morton Ltd (Subsidiary of W.R. Swann and Co.) Woodland Works 716 Penistone Road Sheffield S6 2DF United Kingdom Facility ID Number: F000431	Incoming inspection and storage of raw materials, manufacturing, and in process inspection for the injection moulding of device subcomponents.
Swann-Morton Ltd (Subsidiary of W.R. Swann and Co.) Cobb Works Owlerton Green Sheffield S6 2BJ United Kingdom Facility ID Number: F000431	Packaging.



Original Registration Date: 2018-08-30

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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Certificat d'enregistrement

SYSTEME DE MANAGEMENT QUALITE - ISO 13485 : 2016

Ceci certifie que :
Swann-Morton Limited
Owlerton Green
Scheffield
S6 2BJ
United Kingdom

Numéro d'identification Usine : F000431

Est détenteur du certificat N° : **MDSAP 674417**

La société inscrite sur ce certificat a été auditée et jugée conforme à la norme ISO 13485:2016, y compris aux exigences spécifiques au pays suivantes :

Australie : Règlements 2002 sur les Biens thérapeutiques (Dispositifs Médicaux)- Annexe 3, Chapitre 1 (à l'exception du chapitre 1.6) – Procédure complète d'Assurance Qualité.

Brésil : RDC ANVISA n.67/2009, RDC ANVISA n.665/2022 – Conforme au process de fabrication, RDC ANVISA n.551/2021

Canada : Règlements sur les Dispositifs Médicaux – Chapitre 1 - SOR 98/282

Japon : MHLW Ordonnance ministérielle n°169 (2004), modifié par MHLW Ordonnance ministérielle No 60 (2021), loi PMD

USA : 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – sous-Chapitres A à D

La conception, la fabrication et la distribution des lames chirurgicales, des bistouris à usage unique, des manches et des extracteurs de lame.

Pour et au nom du BSI :

Graeme Tunbrige, Vice-Président Senior – Dispositifs Médicaux

Certificat N° : MDSAP 674417

Location	Activités enregistrées
Swann-Morton Limited Owlerton Green Sheffield S6 2BJ United Kingdom	La conception et la fabrication des lames chirurgicales, des bistouris, des manches et des extracteurs de lames
Swann-Morton Ltd (Subsidiary pf W.R. Swann and Co.) Woodland Works 716 Penistone Road Sheffield S6 2DF United Kingdom	Inspection des matières premières à la livraison et pendant l'entreposage, et lors du process de moulage des sous-composants du dispositif
Swann-Morton Ltd (Subsidiary pf W.R. Swann and Co.) Cobb Works Owlerton Green Sheffield S6 2BJ United Kingdom	Emballage

Date initiale d'enregistrement : 30-08-2018

Date d'effet : 18-11-2018

Date d'expiration : 17-11-2026