

UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No. **UKCA 753776**
Issued To: **Swann-Morton Limited**
Owlerton Green
Sheffield
S6 2BJ
United Kingdom

In respect of:

The design and manufacture of sterile and non-sterile stainless steel and carbon steel surgical blades, scalpels and skin graft blades.

Those Aspects of Annex II concerned with securing and maintaining the sterile condition of sterile suture removers

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-09-10**

Date: **2022-01-07**

Expiry Date: **2026-01-19**

...making excellence a habit.™

Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000

Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.

A member of BSI Group of Companies.

UKCA Certificate - Full Quality Assurance System

Supplementary Information to UKCA 753776

Issued To:

Swann-Morton Limited
Owlerton Green
Sheffield
S6 2BJ
United Kingdom

Device Code	Device Name	Intended purpose per IFU
Class IIa		
MD0106	Single use surgical scalpels and blades	N/A
Class Is		
MD0106	Sterile Suture remover	N/A

First Issued: **2021-09-10**Date: **2022-01-07**Expiry Date: **2026-01-19**

...making excellence a habit.™

Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000

Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.

A member of BSI Group of Companies.

UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

Certificate No: **UKCA 753776**
 Date: **2022-01-07**
 Issued To: **Swann-Morton Limited**
Owlerton Green
Sheffield
S6 2BJ
United Kingdom

Subcontractor:

Service(s) supplied

Andersen Caledonia Limited
 Caledonian House
 Phoenix Crescent
 Strathclyde Business Park, Bellshill
 ML4 3NJ
 United Kingdom

ETO Sterilization

Jewel Blade Ltd
 442 Penistone Road
 Sheffield
 S6 2FU
 United Kingdom

Crucial Supplier

Swann-Morton (Microbiological Laboratory Services)
 Limited
 Owlerton Green
 Sheffield
 S6 2BJ
 United Kingdom

Microbiology Service

...making excellence a habit.™

UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

Certificate No: **UKCA 753776**
 Date: **2022-01-07**
 Issued To: **Swann-Morton Limited**
Owlerton Green
Sheffield
S6 2BJ
United Kingdom

Subcontractor:

Service(s) supplied

Swann-Morton (Services) Limited
 Penn Works
 Owlerton Green
 Sheffield
 South Yorkshire
 S6 2BJ
 United Kingdom

Radiation (Gamma Sterilization)

...making excellence a habit.™

UKCA Certificate - Full Quality Assurance System

Certificate History

Certificate No: **UKCA 753776**
Date: **2022-01-07**
Issued To: **Swann-Morton Limited**
Owlerton Green
Sheffield
S6 2BJ
United Kingdom

Date	Reference Number	Action
10 September 2021	3486655	First Issue; Traceable to MDR 721051
Current	3584737	Amended - Removal of subcontractor Woodland Works

...making excellence a habit.™