

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 00482
Issued To: Swann-Morton Limited
Owlerton Green
Sheffield
South Yorkshire
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

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1995-02-01**

Date: **2020-03-25**

Expiry Date: **2021-05-16**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 00482**
Date: **2020-03-25**
Issued To: **Swann-Morton Limited**
Owlerton Green
Sheffield
South Yorkshire
S6 2BJ
United Kingdom

Subcontractor:	Service(s) supplied
Andersen Caledonia Limited Caledonian House Phoenix Crescent Strathclyde Business Park Lanarkshire ML4 3NJ UK	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

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 00482**
Date: **2020-03-25**
Issued To: **Swann-Morton Limited**
Owlerton Green
Sheffield
South Yorkshire
S6 2BJ
United Kingdom

Subcontractor:

Service(s) supplied

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

Gamma Sterilization

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00482**
 Date: **2020-03-25**
 Issued To: **Swann-Morton Limited**
Owlerton Green
Sheffield
South Yorkshire
S6 2BJ
United Kingdom

Date	Reference Number	Action
01 February 1995	-	Certificate Issue.
05 January 2000	-	Addition of a subcontractor – Swann Morton (Services) Ltd.
12 July 2001	-	Addition of a subcontractor – Swann Morton (Microbiological Laboratory Services) Ltd. Removal of Class I Sterile Devices. 5-year renewal.
15 March 2004	-	Addition of Lance Paragon Products and related subcontractor Jewel Blade Co Ltd. Reissue in new certificate format.
17 May 2006	-	5-year renewal. Certificate reissue in new certificate format.
23 March 2011	7661754	Certificate renewal and removal of Jewel Blade Ltd.
23 March 2015	8292162	Removal of 'also trading as Lance Paragon Ltd' from the name of the company; addition of Jewel Blade Ltd as a crucial supplier.
05 May 2016	8501345	Certificate renewal.
08 February 2019	7779000	Traceable to NB 0086.
Current	3154361	Addition of the subcontractor Andersen Caledonia Limited for ETO Sterilization activity.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

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

Holds Certificate No: **FM 73368**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, manufacture, packaging and distribution of surgical blades, disposable scalpels, handles and blade removers.

For and on behalf of BSI:



Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 2002-12-24

Latest Revision Date: 2018-08-30

Effective Date: 2018-08-30

Expiry Date: 2020-11-17

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