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By Royal Charter

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):

Albert Roossien, Regulatory Lead

First Issued: **1995-02-01** Date: **2019-02-08** Expiry Date: **2021-05-16**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No: **CE 00482**

Date: **2019-02-08**

Issued To: **Swann-Morton Limited**
Owlerton Green
Sheffield
South Yorkshire
S6 2BJ
United Kingdom

Subcontractor:	**Service(s) supplied**
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**
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: **2019-02-08**
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.
Current	7779000	Traceable to NB 0086.

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BSI Migration of Certificates from UK Notified Body (0086) to NL Notified Body (2797)

BSI operates two full scope Notified Bodies, which cover all NBOG codes for the Medical Device Directives (MDD, AIMD, and IVDD):

United Kingdom	**Netherlands**
Notified Body Number 0086	**Notified body number 2797**
BSI Kitemark Court Davy Avenue Milton Keynes MK5 8PP	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam

Please Note: This letter provides validation only where BSI NB 2797 certificate(s) accompany the document.

The named manufacturer has completed migration of the enclosed CE certificate(s), originally issued by BSI UK (0086) Notified Body to BSI Group The Netherlands B.V. which is a European Notified Body designated in The Netherlands for the following three directives: MDD (93/42/EEC), AIMDD (90/385/EEC) and IVDD (98/79/EC).

The migrated certificates retain their original certificate references to ensure traceability and to maintain full visibility of the significant history of the previous certification changes for the product or product family concerned. BSI Group The Netherlands B.V will maintain and continue with the full surveillance audit schedule set previously by BSI UK. The maintained traceability ensures all regulatory requirements under the Directives remain valid and assessed on an ongoing basis and manufacturers do not need to update their labelling immediately.

Your Sincerely

Gary Slack

SVP Notified Body and Brexit Strategist,