



Lloyd's
Register

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

SMI AG
Steinerberg 8
4780 ST VITH
Belgium

has been assessed against the requirements of Annex II (excluding Section 4) of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations. In addition for Class III products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ00001122/B
Original Approval: 16 January 2018
Current Certificate: 30 September 2019
Certificate Expiry: 15 January 2021

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited



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**EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM
CERTIFICATE LRQ 00001122/B SCHEDULE**

**In accordance with the requirements of the Medical Devices
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK
Statutory Instrument 2002 No. 618**

**SMI AG
Steinerberg 8
4780 ST VITH
Belgium**

Scope: Design and Manufacture of sterile synthetic absorbable Sutures and non-absorbable Sutures with or without atraumatic stainless steel needles

Class IIb

Sterile Non-absorbable Stainless Steel Sutures
Sterile Non-absorbable Silk Sutures
Sterile Non-absorbable Polyamide-Nylon Sutures
Sterile Non-absorbable Polypropylene Sutures

Class III Products

SURGICRYL® PGA & SURGICRYL® RAPID
SURGICRYL® 910

EC Design Examination Certificate

0088/00001122/00413
0088/00001122/00422

Schedule Issue: 04

Date of Schedule Issue: 30 September 2019

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited



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EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

**SMI AG
Steinerberg 8
4780 ST VITH
Belgium**

has been assessed against the requirements of Annex V of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ00001122/C
Original Approval: 27 September 2019
Current Certificate: 27 September 2019
Certificate Expiry: 26 September 2022

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom



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EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE CERTIFICATE LRQ00001122/C SCHEDULE

In accordance with the requirements of the Medical Devices
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK
Statutory Instrument 2002 No. 618

SMI AG
Steinerberg 8
4780 ST VITH
Belgium

Scope: Manufacture and supply of sterile surgical instruments

Class I Sterile All aspects of manufacture concerned with securing and maintaining
sterile conditions of:
Disposable skin staple remover
Skin marker

Class IIa
Sterile surgical blades
Sterile skin stapler

Schedule Issue: 01

Date of Schedule Issue: 27 September 2019

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

Certificate of Approval

This is to certify that the Management System of:

SMI AG

Steinerberg 8, 4780 St Vith, Belgium

has been approved by LRQA to the following standards:

EN ISO 13485:2016 | ISO 13485:2016



David Derrick - Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited

Current issue date: 26 February 2019

Expiry date: 11 January 2021

Certificate identity number: 10176608

Certificate Approval No: LRQ00001122/A

Original approval(s):

ISO 13485 – 12 January 2018

Product Approval number: ISO 13485 – 00018921

The scope of this approval is applicable to:

Design, development, manufacture and distribution of sterile and nonsterile medical devices for wound closure including sutures, skin-staplers and staple removers and devices for haemostasis, surgical meshes, skin markers, biopsy devices and surgical blades.



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