

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

**EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE
CERTIFICATE LRQ00001122/C SCHEDULE**

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**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

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