Lloyd's Register
LRQA

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 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:	LRQ 4008223/B
Original Approval:	16 January 2018
Current Certificate:	16 January 2018
Certificate Expiry:	15 January 2021

LRQA Notified Body Number 0088

David Dennis

Issued by: Lloyd's Register Quality Assurance Limited

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

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM
CERTIFICATE LRQ 4008223/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

Class III Products	**EC Design Examination Certificate**
SURGICRYL® PGA & SURGICRYL® RAPID	0088/00001122/00413

Schedule Issue: 01

Date of Schedule Issue: 16 January 2018

LRQA Notified Body Number 0088

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