

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:

ISO 13485:2016

David Denis

David Derrick - Area Operations Manager UK & Ireland Issued by: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

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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