



EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 084219 0003 Rev. 00

Manufacturer:

Leica Microsystems

(Schweiz) AG

Max Schmidheiny Str. 201

9435 Heerbrugg SWITZERLAND

Facility(ies):

Leica Microsystems (Schweiz) AG

Max Schmidheiny Str. 201, 9435 Heerbrugg, SWITZERLAND

Product Category(ies): Surgical microscope systems and their accessories for imaging

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713158274

Valid from:

2019-06-05

Valid until:

2024-05-26

Date.

2019-05-29

Stefan Preiß

1. Punil

Head of Certification/Notified Body