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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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Product Service

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 074765 0021 Rev. 00

Manufacturer: **Leica Microsystems NC, Inc**
4222 Emperor Blvd, Suite 390
Durham NC 27703
USA

Product Category(ies): **Ophthalmic Imaging System using Optical Coherence Tomography**

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.: 713183683

Valid from: 2020-04-16

Valid until: 2024-05-26

Date, 2020-04-16

Christoph Dicks
Head of Certification/Notified Body