



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



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 020011 0048 Rev. 00

Manufacturer: FUJIFILM Corporation
26-30, Nishiazabu 2-Chome
Minato-Ku, Tokyo
106-8620 JAPAN

EC-Representative: FUJIFILM Europe GmbH
Heesenstr. 31,
40549 Düsseldorf,
GERMANY

Product Category(ies): Computed Radiography Console, Diagnostic X-ray
Equipment, Digital Mammography System and
related equipment, Software for Diagnostic
Imaging Workstations, Ultrasound Diagnostic
Imaging Equipment, Endoscopes for medical use
and their related equipment and accessories,
Ultrasound Endoscopes and their related
equipment and accessories

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.

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Valid until: 2022-11-21

Date, 2018-08-28

Stefan Preiß

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFICADO ◆ CERTIFICAT



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Facility(ies):

FUJIFILM Corporation
 26-30, Nishiazabu 2-Chome, Minato-Ku, Tokyo,
 106-8620 JAPAN

FUJIFILM Corporation
 798, Miyanodai, Kaisei-Machi, Ashigarakami-Gun,
 Kanagawa, 258-8538 JAPAN

-/-

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE ◆ ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE ◆ ZERTIFIKAT ◆ CERTIFICATE ◆