Benannt durch/Designated by
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 020011 0048 Rev. 01

Manufacturer:

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

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.

Report No.: **JAQ235040080**

Valid from: **2020-02-18**
Valid until: **2024-05-26**

Digitally signed by Botnaru Andrei
Date: 2024.01.05 10:11:44 EET
Reason: MoldSign Signature
Location: Moldova

Date, **2020-02-18**

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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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

-/-

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