



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 17 07 20011 043

**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.

**Report No.:** JAQ235030764

**Valid from:** 2017-11-22  
**Valid until:** 2022-11-21

**Date,** 2017-11-07

Stefan Preiß



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

Page 1 of 2



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 17 07 20011 043**

**Facility(ies):**

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

**FUJIFILM Corporation, Medical Systems Research  
& Development Center  
798, Miyanodai, Kaisei-Machi, Ashigarakami-Gun,  
Kanagawa, 258-8538 JAPAN**