



# Certificate

No. Q5 020011 0062 Rev. 00

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

**Certification Mark:**



**Scope of Certificate:** Design and Development, Distribution of Digital Radiography and Accessories,  
Computed Radiography and Accessories,  
Imaging Plates for Computed Radiography,  
Digital Mammography and Accessories,  
Diagnostic X-Ray Equipment and Accessories,  
Workstations,  
Medical Endoscopes and Peripherals and Accessories,  
Ultrasonic Endoscopes and Peripherals and Accessories,  
Automatic Endoscope Reprocessor,  
Ultrasonic Diagnostic Imaging Equipment and Accessories,  
Medical Imager and Accessories,  
Cassette,  
Clinical Chemistry Analyzer,  
Densitometry Analyzer,  
Blood Collection Kit for Blood Test,  
and Reagents and Related Products for In-Vitro Diagnostics;  
Categorized as Dry Chemistry and Immunoassay Tests,  
Distribution of Film Processor

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 020011 0062 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5 020011 0062 Rev. 00)

**Report No.:** JA1866259

**Valid from:** 2023-02-20  
**Valid until:** 2024-10-31

**Date,** 2023-02-20

Christoph Dicks  
Head of Certification/Notified Body

# Certificate

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## Applied Standard(s):

EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

## Facility(ies):

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

Design and Development of Digital Radiography and Accessories,  
Computed Radiography and Accessories,  
Imaging Plates for Computed Radiography,  
Digital Mammography and Accessories,  
Diagnostic X-Ray Equipment and Accessories, Workstations,  
Medical Endoscopes and Peripherals and Accessories,  
Ultrasonic Endoscopes and Peripherals and Accessories,  
Automatic Endoscope Reprocessor,  
Ultrasonic Diagnostic Imaging Equipment and Accessories,  
Medical Imager and Accessories,  
Cassette,  
Clinical Chemistry Analyzer, Densitometry Analyzer,  
Blood Collection Kit for Blood Test,  
Reagents and Related Products for In-Vitro Diagnostics;  
Categorized as Dry Chemistry and Immunoassay Tests  
Quality Assurance of Film Processor

**FUJIFILM SOFTWARE CO., LTD.**  
**798, Miyanodai, Kaisei-Machi, Ashigarakami-Gun, Kanagawa,**  
**258-8538 JAPAN**

Design and Development of  
Digital Radiography and Accessories,  
Computed Radiography and Accessories,  
Digital Mammography and Accessories,  
Diagnostic X-Ray Equipment and Accessories,  
Medical Endoscopes and Peripherals and Accessories,  
Ultrasonic Endoscopes and Peripherals and Accessories,  
Automatic Endoscope Reprocessor,  
Ultrasonic Diagnostic Imaging Equipment and Accessories,  
Medical Imager and Accessories,  
Clinical Chemistry Analyzer

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

Design and Development, Distribution of Workstations

# Certificate

No. Q5 020011 0062 Rev. 00

## Facility(ies):

**FUJIFILM Corporation**  
**MID TOWN WEST, 9-7-3, Akasaka, Minato-Ku, Tokyo,**  
**107-0052 JAPAN**

Distribution of Digital Radiography and Accessories,  
Computed Radiography and Accessories,  
Imaging Plates for Computed Radiography,  
Digital Mammography and Accessories,  
Diagnostic X-Ray Equipment and Accessories,  
Medical Imager and Accessories, Cassette,  
Workstation,  
Medical Endoscopes and Peripherals and Accessories,  
Ultrasonic Endoscopes and Peripherals and Accessories,  
Automatic Endoscope Reprocessor,  
Ultrasonic Diagnostic Imaging Equipment and Accessories,  
Clinical Chemistry Analyzer,  
Densitometry Analyzer,  
Blood Collection Kit for Blood Test,  
Reagents and Related Products for In-Vitro Diagnostics;  
Categorized as Dry Chemistry and Immunoassay Tests

**FUJIFILM SOFTWARE CO., LTD.**  
**NOMURAFUDOSANSHINYOKOHAMA BLDG. 7F., 2-10-23,**  
**Shin-Yokohama, Kohoku-Ku, Yokohama, Kanagawa,**  
**222-0033 JAPAN**

Design and Development of Workstations

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