



Product Service

Certificate

No. Q8 020011 0046 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, Data Management System/Network system, 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). See also notes overleaf.

Report No.: JAQ235032836
Valid from: 2018-11-01
Valid until: 2021-10-31

Date, 2018-08-27

Stefan Preiß

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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
 Shinyokohama TECH Bldg. B-kan 15F., 3-9-1,
 Shin-Yokohama, Kohoku-Ku, Yokohama, Kanagawa,
 222-0033 JAPAN

FUJIFILM Corporation
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 107-0052 JAPAN

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

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

FUJIFILM SOFTWARE CO., LTD.
 798, Miyanodai, Kaisei-Machi, Ashigarakami-Gun, Kanagawa,
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FUJIFILM Corporation
 210 Nakanuma, Minamishigara-shi, Kanagawa, 250-0193
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FUJIFILM Techno Products Co., Ltd.
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FUJIFILM Corporation
 577, Ushijima, Kaisei-Machi, Ashigarakami-Gun, Kanagawa,
 258-8577 JAPAN

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