

CERTIFICATE

Number: 2008457

The management system of the organization(s) and locations mentioned on the addendum belonging to:

FUJIFILM Corporation

26-30 Nishiazabu
2-Chome Minato-Ku
Tokyo 106-8620
Japan

including the implementation meets the requirements of the standard:

ISO 13485:2003

Scope:

Design, production, sales and distribution of Medical X-ray films and Imaging films

Certificate expiry date: 1 March 2019

Certificate effective date: 21 March 2016

Certified since: 1 April 2001

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



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ADDENDUM

To certificate: 2008457

The management system of the organization(s) and/or location(s) of:

FUJIFILM Corporation

26-30 Nishiazabu 2-Chome, Minato-Ku

Tokyo 106-8620

Japan

Certified additional organization(s) and/or locations:

Organization/Location

Different scope

Fujinomiya Factory
200 Onakazato, Fujinomiya
Shizuoka 418-8666 Japan

Design control, Production Engineering, Purchasing of Medical X-ray films and Imaging films, Human resources, Production planning, Quality improvement, Incoming inspection, Supplier control

Medical Systems R&D Center; includes:
Medical Systems Business Division
798, Miyanodai, Kaise-Machi
Ashigarakami-Gun
Kanagawa 258-8538 Japan

QA/RA departments
Marketing department
Service Engineering

FUJIFILM SHIZUOKA Co. Ltd. (FFSH)
200 Onakazato, Fujinomiya,
Shizuoka 418-8666 Japan

Production

Fujifilm Engineering Co. Ltd (FEC)
200 Onakazato, Fujinomiya,
Shizuoka 418-8666 Japan

Calibration
Maintenance of facilities (including equipment and installation)

Addendum expiry date: 1 March 2019
Addendum effective date: 21 March 2016