

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 13485:2016 EN ISO 13485:2016

Scope:

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

Certificate expiry date: 1 March 2022

Certificate effective date: 5 March 2019

Certified since: 1 April 2001

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

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



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 organization(s) and/or locations:

Different scope

Functional Materials Manufacturing
Headquarters
Fujinomiya Plant
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
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)

Modality Solution Division
Medical Systems Business Division
9-7-3 Akasaka, Minato-ku
Tokyo 107-0052 Japan

Marketing

Addendum expiry date: 1 March 2022

Addendum effective date: 5 March 2019