

# 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