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 and distribution of Medical X-ray films and Imaging films

Certificate expiry date: 1 March 2028
Certificate effective date: 1 March 2025
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.M. McKenzie 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

FUJIFILM Corporation Material Manufacturing Headquarters **Engineering Unit** 200 Onakazato, Fujinomiya Shizuoka 418-8666 Japan

Design control, Production, Purchasing of Medical X-ray films and Imaging films

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

FUJIFILM MATERIAL MANUFACTURING CO., LTD Shizuoka Area 200 Onakazato, Fujinomiya, Shizuoka 418-8666 Japan

Complaint Handling, Vigilance, Post Market Surveillance for Medical X-ray films and Imaging films

Production of Medical X-ray films and Imaging films

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

Calibration, Maintenance of facilities and equipment for Medical X-ray films and Imaging films production

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

Order processing, Control of product information provision (website, marketing material, etc.) for Medical X-ray films and Imaging films production

Addendum expiry date: 1 March 2028 Addendum effective date: 1 March 2025