



Certificate

Standard **ISO 13485:2016, JIS Q 13485:2018**

Certificate Registr. No. 81 105 1734349

Certificate Holder: **KONICA MINOLTA, INC.**
1 Sakura-machi, Hino-shi, Tokyo, 191-8511 Japan

including the locations according to annex

Scope: Design, Development and Manufacture of Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems), Radiographic Film Processors, Diagnostic Ultrasound Systems and Transducers, Picture Archiving and Communication Systems (PACS), Software for Picture Archiving and Communication Systems (PACS), Print Management Systems, Pulse Oximeters and Jaundice Meters.
Design, Development and Manufacture of Fluoroscopic Image Storage Devices (Plate, Cassette and Cassette Plate)
Design, Development, Manufacture and Distribution of Laser Imagers, Diagnostic X-ray Systems
Distribution of Medical Imaging Films, X-ray Films (X-ray Films for General Radiography, X-ray Films for Photofluorography and Dental X-ray Films for General Use)

Proof has been furnished by means of an audit that the requirements of ISO 13485:2016, JIS Q 13485:2018 are met.

Validity: The certificate is valid from 2018-07-18 until 2021-01-16.
First certification 2018

2018-07-18


TÜV Rheinland Japan Ltd.
3-19-5 Shin-Yokohama, Kohoku-ku,
Yokohama 222-0033, Japan



Annex to certificate

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| No. | Location | Scope |
|-----|--|---|
| /01 | <p>KONICA MINOLTA, INC. Hino site</p> <p>KONICA MINOLTA TECHNOPRODUCTS CO., LTD. Hino site</p> <p>1 Sakura-machi, Hino-shi, Tokyo, 191-8511, Japan</p> | <p>Design, Development and Manufacture of Diagnostic Ultrasound Systems and Transducers, Picture Archiving and Communication Systems (PACS) and Fluoroscopic Image Storage Devices (Plate and Cassette Plate)</p> <p>Design and Development of Software for Picture Archiving and Communication Systems (PACS)</p> <p>Distribution of Laser Imagers, Diagnostic X-ray Systems</p> <p>Distribution of Medical Imaging Films, X-ray Films (X-ray Films for General Radiography, X-ray Films for Photofluorography and Dental X-ray Films for General Use)</p> <p>Manufacture of Pulse Oximeters</p> |
| /02 | <p>KONICA MINOLTA, INC. Hachioji site</p> <p>2970 Ishikawa-machi, Hachioji-shi, Tokyo, 192-8505, Japan</p> | <p>Design and Development of Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems), Laser Imagers, Radiographic Film Processors, Diagnostic X-ray Systems, Picture Archiving and Communication Systems (PACS), Print Management Systems, Pulse Oximeters and Jaundice Meters</p> <p>Design and Development of Fluoroscopic Image Storage Devices (Cassette and Cassette Plate)</p> |

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| No. | Location | Scope |
|-----|---|--|
| /03 | KONICA MINOLTA TECHNOPRODUCTS CO., LTD. Sayama site 2-2-1 Hirosedai, Sayama-shi, Saitama, 350-1328, Japan | Manufacture of Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems), Laser Imagers, Radiographic Film Processors, Diagnostic X-ray Systems, Diagnostic Ultrasound Systems, Picture Archiving and Communication Systems (PACS), Software for PACS, Print Management Systems and Jaundice Meters Manufacture of Fluoroscopic Image Storage Devices (Plate, Cassette and Cassette Plate) |

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| No. | Location | Scope |
|-----|--|--|
| /04 | KONICA MINOLTA TECHNOPRODUCTS CO., LTD. Kuki site 6201-6 Sanga, Shobu-cho, Kuki- shi, Saitama, 346-0104, Japan | Distribution of Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems) and Laser Imagers Distribution of Medical Imaging Films and X-ray Films (X-ray Films for General Radiography, X-ray Films for Photofluorography and Dental X-ray Films for General Use) |

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Yokohama 222-0033, Japan



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