



KONICA MINOLTA

EU DECLARATION OF CONFORMITY

Manufacturer

Name KONICA MINOLTA, INC.
Address 1 Sakura-machi, Hino-shi, Tokyo, 191-8511, Japan
Single Registration Number Pending

declares, sole responsibility, that the following product

Generic Device Group: X-ray Films
Type: MEDICAL IMAGING FILM
Model (Product Name): SD-Q, SD-QM, SD-P, SD-PM
Basic UDI-DI: 4560141920000178A
Intended Purpose: This device is intended to reproduce a radiography image from X-ray diagnostic image data by the Laser Imager.
Classification: Class I, Rule 1, according to Annex VIII of REGULATION (EU) 2017/745

Including each Lot number shown in other page(s) of this declaration,

referred to in this declaration conforms with the following EU law(s):

REGULATION (EU) 2017/745, confirmed by the procedure of its Annex IX

and conforms with the following standard(s):

EN ISO 13485:2016, EN ISO 14971:2012, EN 1041:2008,
EN ISO 15223-1:2016, EN 62366:2008

and that this declaration is valid upon approval for release of each product.

EU Representative

Name Konica Minolta Business Solutions Europe GmbH
Address Capellalaan 65, 2132 JL, Hoofddorp, The Netherlands
Single Registration Number NL-AR-000002026

Signed for and on behalf of manufacturer:

Tokyo Japan, 2021-04-22
(Place and date of issue)
HAJIME NOZAWA
General Manager,
Quality Assurance Operations
Healthcare Business Unit
Healthcare Business Headquarters
(Name, function)

(Signature of equivalent authorized by the manufacturer)



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