



KONICA MINOLTA

# EU DECLARATION OF CONFORMITY

## Manufacturer

Name KONICA MINOLTA, INC.  
Address 1 Sakura-machi, Hino-shi, Tokyo, 191-8511, Japan  
Single Registration Number JP-MF-000008214

## 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

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, 2021-08-24  
(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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Model / Description	Commodity Code	Lot Number (from)	Lot Number (to)
SD-Q 8X10" MEDICAL FILM 125 SH	A3R5	024326-224	029999-299
SD-Q 10X12" MEDICAL FILM 125 SH	A3R6	024326-221	029999-299
SD-Q 11X14" MEDICAL FILM 50 SH	A3R7	024328-203	029999-299
SD-Q 11X14" MEDICAL FILM 125 SH	A3R8	024327-206	029999-299
SD-Q 14X14" MEDICAL FILM 125 SH	A3R9	024328-202	029999-299
SD-Q 14X17" MEDICAL FILM 50 SH	A3RC	024328-201	029999-299
SD-Q 14X17" MEDICAL FILM 125 SH	A3RD	024322-202	029999-299
SD-QM 11X14" MEDICAL FILM 125 SH	A3RP	024298-201	029999-299
SD-QM 8X10" MEDICAL FILM 125 SH	A3RJ	024298-201	029999-299
SD-QM 10X12" MEDICAL FILM 125 SH	A3RK	024298-202	029999-299
SD-P 8X10" MEDICAL FILM 125 SH	A5FH	022234-243	029999-299
SD-P 10X12" MEDICAL FILM 125 SH	A5FJ	022234-233	029999-299
SD-P 11X14" MEDICAL FILM 125 SH	A5FM	022234-242	029999-299
SD-P 11X14" MEDICAL FILM 50 SH	A5FK	022234-242	029999-299
SD-P 14X17" MEDICAL FILM 50 SH	A5FP	022234-238	029999-299
SD-P 14X14" MEDICAL FILM 125 SH	A5FN	022234-243	029999-299
SD-P 14X17" MEDICAL FILM 125 SH	A5FR	022234-238	029999-299
SD-PM 8X10" MEDICAL FILM 125 SH	A5G4	022234-212	029999-299
SD-PM 10X12" MEDICAL FILM 125 SH	A5G5	022234-213	029999-299
SD-PM 11X14" MEDICAL FILM 50 SH	A5G6	022234-212	029999-299
SD-PM 11X14" MEDICAL FILM 125 SH	A5G7	022234-214	029999-299