



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, SD-Q2
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 14971:2019+A11:2021, EN 1041:2008+A1:2013,
EN ISO 15223-1:2021, EN 62366-1:2015+A1:2020

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, 2022-06-17
(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	024321-234	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
SD-Q2 8X10" DL-PACK NIF 125S (IMG.FILM)	AE5X	80906	89999
SD-Q2 10X12" DL-PACK NIF 125S (IMG.FILM)	AE5Y	80905	89999
SD-Q2 11X14" 50 (IMG.FILM)	AE61	80905	89999
SD-Q2 11X14" DL-PACK NIF 125S (IMG.FILM)	AE62	80905	89999
SD-Q2 14X14" DL-PACK NIF 125S (IMG.FILM)	AE63	80905	89999
SD-Q2 14X17" 50 (IMG.FILM)	AE64	80902	89999
SD-Q2 14X17" DL-PACK NIF 125S (IMG.FILM)	AE65	80901	89999

