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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-S	
Basic UDI-DI:	4560141920000498P	
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	
Lot Number:	from 047446-203-A-001 to 049999-299E-999	(A76F: 8X10")
	from 047488-202-A-002 to 049999-299E-999	(A76G: 10X12")
	from 047489-201-A-001 to 049999-299E-999	(A76H: 11X14")
	from 047488-213-C-003 to 049999-299E-999	(A76J: 14X17")

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, 2022-01-18
(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)