



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)