Document No. 17ED V.10

KONICA MINOLTA

EU DECLARATION OF CONFORMITY

Manufacturer

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

declares, sole responsibility, that the following product

GMDN term: Diagnostic-imaging photographic film, self-developing
GMDN code: 40983
Generic Device Group: X-ray Films
Type: MEDICAL IMAGING FILM

Model	Size		SD-Q (SDQ)	SD-QM (SDQM Prime)	SD-P (SDP)	SD-PC (SDPC)	SD-PM (SDPM)
Lot Number	08x10	from	023736-222C		022209-209D		022208-215B
		to	023999 299 E		022999 299 E		022999 299 E
	10x12	from	023736-222D				022208-210C
		to	023999 299 E				022999 299 E
	14x11	from	023715-205A	023710-211E	022209-202C	032208-204D	022208-215E
		to	023999 299 E	023999 299 E	022999 299 E	032999 299 E	022999 299 E
	14x14	from			022209-208C		
		to			022999 299 E		
	14x17	from	023730-206A		022209-204C		
		to	023999 299 E		022999 299 E		
	14x17 (50)	from	023725-207A		022210-211B		
		to	023999 299 E		022999 299 E		

Classification: Class I, Rule 1, 93/42/EEC

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

DIRECTIVE 93/42/EEC, confirmed by the procedure of its Annex VII

and conforms with the following standard(s):

EN ISO 13485:2012+AC:2012, EN ISO 14971:2012, EN 62366:2008, EN 1041:2008, EN 980:2008, EN ISO 15223-1:2016

and that this declaration is valid upon approval for release of each lot.
The manufacturer will keep on file for review the technical documentation.

EU Representative

Name Konica Minolta Business Solutions Europe GmbH
Address Hoogoorddreef 9, 1101 BA Amsterdam, The Netherlands

Signed for and on behalf of manufacturer:

Tokyo Japan, 2017-12-27
(Place and date of issue)
YASUSHI YAMANAKA
General Manager,
Quality Assurance Operations
Healthcare Business Unit
Healthcare Business Headquarters
(Name, function)

(Signature of equivalent authorized by the manufacturer)

Digitally signed by Ciudin Ion
Date: 2023.02.21 09:22:46 EET
Reason: MoldSign Signature
Location: Moldova