

KONICA MINOLTA

EC DECLARATION OF CONFORMITY

Document No. 49ED V.01
Manufacturer
Name KONICA MINOLTA, INC.
Address 1 Sakura-machi, Hino-shi, Tokyo, 191-8511, Japan

declares, sole responsibility, that the following product

GMDN term: 40980
GMDN code: X-Ray Film, diagnostic imaging, medical non-screen
Generic Device Group: X-ray Film
Type: MEDICAL IMAGING FILM
Model: SD-S
Classification: Class I, Rule 1, 93/42/EEC
Lot Number: from 000001-001-A-001 to 999999-999-E-999

This declaration is valid upon approval for release of each lot.

referred to in this declaration conforms with the following directive(s) :
93/42/EEC, confirmed by the procedure of Annex VII of 93/42/EEC

and conforms with the following standard(s):
EN ISO 13485:2003, EN ISO 14971:2009, EN 1041:2008, EN 980:2008
EN ISO 4090:2004, EN 62366:2008

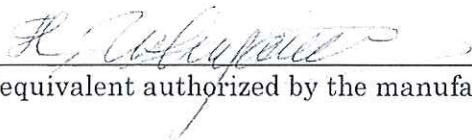
The manufacturer will keep on file for review the technical documentation.

EU Representative

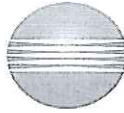
Name KONICA MINOLTA MEDICAL & GRAPHIC IMAGING EUROPE B.V.
Address Frankfurtstraat 40, 1175 RH Lijnden, The Netherlands

Signed for and on behalf of manufacturer:

Tokyo Japan, 2013-04-08
(Place and date of issue)
HIROYUKI USHIROYAMA
General Manager,
Quality Assurance Operations
Healthcare Company
(Name, function)


(Signature of equivalent authorized by the manufacturer)





KONICA MINOLTA

EC DECLARATION OF CONFORMITY

Document No. 17ED V.07
 Manufacturer
 Name KONICA MINOLTA, INC.
 Address 1 Sakura-machi, Hino-shi, Tokyo, 191-8511, Japan

declares, sole responsibility, that the following product

GMDN term: Film, diagnostic imaging, photographic
 GMDN code: 40974
 Generic Device Group: X-ray Film
 Type: MEDICAL IMAGING FILM

Model		SD-P	SD-PC	SD-PM
Lot Number	from	0003	0008	0007
	to	9993	9998	9997
	from	022012 201	032012 201	022012 201
	to	029999 299	039999 299	029999 299

Model		SD-Q	SD-QC	SD-QM
Lot Number	from	0002	0006	0005
	to	9992	9996	9995
	from	023000 201	033000 201	023000 201
	to	029999 299	039999 299	029999 299

Classification: Class I, Rule 1, 93/42/EEC
 This declaration is valid upon approval for release of each lot.

referred to in this declaration conforms with the following directive(s) :
 93/42/EEC, confirmed by the procedure of Annex VII of 93/42/EEC

and conforms with the following standard(s):
 EN ISO 13485:2012, EN ISO 14971:2012, EN 62366:2008, EN 1041:2008, EN 980:2008

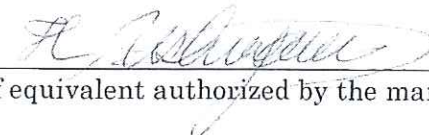
The manufacturer will keep on file for review the technical documentation.

EU Representative

Name KONICA MINOLTA MEDICAL & GRAPHIC IMAGING EUROPE B.V.
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Tokyo Japan, 2013-04-08
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