

Konica Minolta Medical & Graphic, Inc. 1 Sakura-machi, Hino-shi, Tokyo 191-8511 Japan

DECLARATION OF CONFORMITY

(in accordance with ZLG 3.9 A 4 and ISO/IEC 17050-1)

No.

CE17D V.01

Manufacturer

Name Address KONICA MINOLTA MEDICAL & GRAPHIC, INC.

1 Sakura-machi, Hino-shi, Tokyo 191-8511 Japan

declares, sole responsibility, that the following product

Generic Device Group: X-ray Film

Type:

MEDICAL IMAGING FILM

Model		SD-P	SD-PC	SD-PM	SD-Q	SD-QC	SD-QM
Lot Number	from	301 399	801 899	701 799	201 299	601 699	501 599
	from	901			200.		
	to	999					

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 14971:2000+A1:2003

EN 980:2003, EN 1041:1998

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

EU Representative

KONICA MINOLTA MEDICAL & GRAPHIC IMAGING EUROPE B.V.

Frankfurtstraat 40, 1175 Lijnden, The Netherlands

Signed for and on behalf of manufacturer:

Tokyo Japan, 7th August, 2008

(Place and date of issue)

YOSHITAKA YAMADA

General Manager.

Quality Assurance Center <u>Asslutate Jamada</u>
(Name, function) (Signature of equivalent authorized by the manufacturer)

