

EC Declaration of Conformity

Decl.2A-01-13

Manufacturer: FUJIFILM Corporation
Address: 26-30, Nishiazabu 2-chome, Minato-ku,
Tokyo 106-8620, JAPAN
Authorized Representative: FUJIFILM Europe GmbH
Address: HEESENSTRASSE 31
40549 DUESSELDORF, GERMANY
Product(s): Fuji Medical X-ray Film
Model No.: See Annex I
UMDNS: 14481
Applicable Product Units:
Classification (MDD, Annex IX): Class II a (Rule 16)

We herewith declare that the above mentioned product(s) meets the provisions of the following EC Council Directive and Standards.

Directive:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Standards:

EN ISO 13485: 2003 Medical devices - Quality management systems - Requirements for regulatory purpose
EN ISO 14971:2007 Medical devices - Application of risk management to medical devices
EN ISO 4090:2001 Photography-Medical radiographic cassettes/screens/films and hard-copy imaging films-Dimensions and specifications
EN 980:2008 Symbols for use in the labelling of medical devices
EN 1041:2008 Information supplied by the manufacturer of medical devices
EN 20780:1993 Packaging-pictorial marking for handling of goods

Notified Body: KEMA Quality B.V. (Notified Body Number 0344)

Utrechtseweg 310, 6812 AR Amhem P.O.Box 5185, 6802 ED Amhem, The Netherlands

EC Certificate: 76910CE01

Conformity Assessment Procedure: Annex V + VII

Place Kanagawa, JAPAN

Date 2011-11-25



Yasuo Nagashima
Senior Manager, Regulatory Affairs
Quality Assurance Division
Medical Systems Research & Development Center
FUJIFILM Corporation

Annex I to EC Declaration of Conformity

Quality Assurance Division
Medical Systems Research & Development Center
FUJIFILM Corporation

Please refer to the following additional information on EC Declaration of Conformity. This information is to be maintained with corresponding EC Declaration of Conformity.

EC Declaration of Conformity No. : Decl.2A-01-13

Material Description(s) applicable to
EC Declaration of Conformity :

Super RX
Super RX-N
RX-U
New RX-U
UR-1
UR-2
UR-3
Super HR-S
Super HR-HA
Super HR-E
Super HR-T
Super HR-U
Super HR-A
PX
PX-C
UM-MA
AD-M
X-STAR HQ
GREEN-STAR HQ