FUJIFILM

FUJIFILM Corporation
26-30, NISHIAZABU 2-CHOME, MINATO-KU,
TOKYO 106-8620 JAPAN

EC Declaration of Conformity

Decl.1-01-21

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 Imaging Film
Model No.:	See Annex I
UMDNS Code:	17174
GMDN Code:	40983
Applicable Product Units:	See Annex I
Classification (MDD, Annex IX):	Class I (Rule 1)

We, Fujifilm Corporation, herewith declare under our sole responsibility that the product(s) identified in this declaration conforms to the provisions of the following Directives and Standards.

Directive:
Medical Device Directive: 93/42/EEC and their Annexes

Standards:
EN ISO 13485: 2016
EN ISO 14971:2012

Digitally signed by Rotari Vladimir
Date: 2021.04.04 13:45:25 EEST
Reason: MoldSign Signature
Location: Moldova

Conformity Assessment Procedure: Annex VII

Signed for and on behalf of FUJIFILM Corporation

Place and Date of issue

Kanagawa, JAPAN

2019-04-01

Signature :

Name : Naotake Mitsumori
Function: General Manager
Quality Assurance and Regulatory Affairs Division
Medical Systems Business Division
FUJIFILM Corporation

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2019-04-01

Annex I to EC Declaration of Conformity

Quality Assurance and Regulatory Affairs Division
Medical Systems Business Division
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.1-01-21

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

DI-AT
DI-AL
DI-HL
DI-HLc
DI-ML
MDI-HLJ
DI-HT