FUJIFILM

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

EN

EU Declaration of Conformity

18-CEM-01-F

Manufacturer:	FUJIFILM Corporation
single registration number (SRN)	TBD
Address:	26-30, Nishiazabu 2-chome, Minato-ku, Tokyo 106-8620, JAPAN
Authorized Representative:	FUJIFILM Europe GmbH
single registration number (SRN)	TBD
Address:	Heesenstrasse 31 40549 Duesseldorf, GERMANY
Basic UDI-DI:	454741010100000000000523K
Trade name:	FUJI MEDICAL DRY LASER IMAGER DRYPIX EDGE
Model Number:	DRYPIX8000
Applicable Products:	xxx28676 or later
Classification (MDR, Annex VIII):	Class I (Rule 13)

We, FUJIFILM Corporation, herewith declare in our sole responsibility that the product(s) identified in this declaration conforms to the provisions of the following Regulation(s) and Directive(s).

Regulation:
Medical Device Regulation: REGULATION (EU) 2017/745 and their Annexes.
Directive:
RoHS Directive: 2011/65/EU,(EU)2015/863
Common specifications ('CS'):
No references to any CS

Conformity Assessment Procedure for Regulation (EU) 2017/745 :
Annex IV

Place and Date of issue

Kanagawa, JAPAN

2021-05-21

Signature :

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

Digitally signed by Botnaru Andrei
Date: 2024.04.08 10:47:26 EEST
Reason: MoldSign Signature
Location: Moldova