

EC Declaration of Conformity

06-CEM-25-P

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 DRY LASER IMAGER
Model No.:	DRYPIX 4000
Marketing names/variants:	DRYPIX Plus
UMDNS Code :	17904
GMDN Code:	35580
Applicable Product Units:	Annex II
Manufacturing sites	Annex II
Classification (MDD, Annex IX):	Class I (Rule 12)

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
 RoHS Directive: 2011/65/EU

Standards:
 MDD: EN ISO 13485:2016
 EN ISO 14971:2012
 EN 60601-1:2006/A1:2013
 EN 60601-1-2:2007/AC:2010
 EN 62304:2006/AC:2008
 EN 62366:2008

RoHS: EN 50581:2012

Conformity Assessment Procedure: Directive 93/42/EEC Annex VII

Place and Date of issue

Kanagawa, JAPAN

2018-11-15

Signature :



Name : Naotake Mitsumori

Function: General Manager

Quality Assurance and Regulatory Affairs Division
 Medical Systems Business Division
 FUJIFILM Corporation

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 Declaration of Conformity.

Declaration of Conformity No. : 06-CEM-25-P

Material Description applicable to
Declaration of Conformity :

DRYPIX PLUS 100V H : E
DRYPIX PLUS 100V 2T BH : E
DRYPIX PLUS 100V 3T BHH : E
DRYPIX PLUS 200V H : E
DRYPIX PLUS 200V 2T BH : E
DRYPIX PLUS 200V 2T 6H : E
DRYPIX PLUS 200V 3T 6BH : E
DRYPIX PLUS 200V 3T BHH : E
DRYPIX PLUS 200V 2T 6H : == E
DRYPIX PLUS 200V 3T 6BH : == E
DPX 4000 SRT E
DPX 4000 FLOOR FIX KIT E
DPX PLUS TRAY : E

2018-11-15

Annex II to EC Declaration of Conformity

Quality Assurance and Regulatory Affairs Division
Medical Systems Business Division
FUJIFILM Corporation

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Declaration of Conformity No. : 06-CEM-25-P

Applicable Product Units to
Declaration of Conformity:

Serial No. ***14056 to ***14065 (*1)

Serial No. ***14154 to ***14160 (*1)

Serial No. ***14323 to ***19999 (*1)

Serial No. ***00793 to ***09999 (*2)

Manufacturing sites

*1 FUJIFILM IMAGING SYSTEMS (SUZHOU) CO.,LTD.

*2 FUJIFILM Techno Products Co.,Ltd.