

EC Declaration of Conformity

07-CEM-03-S

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):	FCR CAPSULA XL II
Model No.:	CR-IR 359
UMDNS Code :	17904
GMDN Code:	17904
Applicable Product Units:	Annex II
Classification (MDD, Annex IX):	Class IIa (Rule 16)

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 62304:2006/AC:2008
EN 62366:2008
EN 60601-1-2:2014

RoHS: EN 50581:2012

EC Certificate for Directive 93/42/EEC: G1 020011 0048
Conformity Assessment Procedure: Annex II excluding (4)
Notified Body: TÜV SÜD Product Service GmbH (Notified Body Number 0123)
Ridlerstr. 65, 80339 München, Germany

Place and Date of issue

Kanagawa, JAPAN

2018-12-21

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. : 07-CEM-03-S

Material Description applicable to
Declaration of Conformity :

IR 355 FLOOR FIX KIT RH E
IR 355 STAND =E
IR 355 STAND == E
IR 355 CASSETTE RACK = E
IR 355 CASSETTE RACK == E
IR 355 CASSETTE RACK FOR LC E
IR 355 CPU FLOOR MOUNT KIT E
IR CPU FLOOR MOUNT KIT EU E
IR 355 ARM FOR LCD MONITOR E
IR 355 STAND WALL FIX KIT E
IR 355 MBL KIT E
IR 359 50MICRON UPGRADE KIT E
IR 359 50MICRON UPGRADE LIC PH
IR 346 AC CORD 200-240V UK E
IR 346 AC CORD 200-240V E
CR IR 359 RU2 : E
CR IR 359 RU2 E
IR 359 50MICRON UPGRADE KIT=E
IR 359 50MICRON UPGRADE KIT==E
HIGH CAP XLR : E
CR IR 359 RU2 USA 1 : E
CR IR 359 RU2 USA 2 : E
CR IR 359 RU2 : PH

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. : 07-CEM-03-S

Applicable Product Units to

Declaration of Conformity:

Serial No. *** 41275 or later (*1)

Serial No. *** 71200 or later (*2)

Manufacturing sites

*1 : FUJIFILM Techno Products Co.,Ltd.

*2 : FUJIFILM IMAGING SYSTEMS (SUZHOU) CO.,LTD.