

# EC Declaration of Conformity

11-CEM-01-V

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 PRIMA T  
Model No.: CR-IR 392  
Marketing names/variants: FCR PRIMA T, FCR PRIMA T2  
FCR PRIMA T PLUS, FCR PRIMA Tm  
UMDNS Code : 17904  
GMDN Code: 17904  
Applicable Product Units: Annex II  
Classification (MDD, Annex IX): Class II a (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 60601-1-2:2014  
EN 62304:2006/AC:2008  
EN 62366:2008

RoHS: EN 50581:2012

EC Certificate for Directive 93/42/EEC: G1 020011 0048  
Conformity Assessment Procedure: Directive 93/42/EEC 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. : 11-CEM-01-V

Material Description applicable to  
Declaration of Conformity :

CR IR 392 RU = : E  
CR IR 392 RU PNTM = :E  
CR IR 392 RU PNTM = USA : E  
CR IR 392 RU PNTM INC = :E  
CR IR 392 RU2 PNTM = :E  
CR IR 392 RU2 PNTM INC = :E  
CR IR 392 RU2 PLUS PNTM = : E  
CR IR 392 RU2 PNTM == :E  
CR IR 392 RU2 PNTM INC == :E  
IR 392 UPGRADE KIT = E  
IR 346 AC CORD 200-240V E  
IR 346 AC CORD 200-240V UK E  
IR 346 AC CORD 100-120V UL E  
IR TABLE FIX KIT = E  
IR 392 TABLE FIX KIT = E  
IR 392 ADD STAND FOR LCD = E  
IR 391 CASSETTE RACK = E  
IR 355 CASSETTE RACK FOR LC E  
IR 355 ARM FOR LCD MONITOR E  
IR 355 STAND WALL FIX KIT E  
IR 355 CPU FLOOR MOUNT KIT E  
IR CPU FLOOR MOUNT KIT EU E  
IR 392 SUPPOT BAR FOR LC = E  
HIGH CAP XR : E  
CR IR 392 RU2 M PNTM = : E  
CR IR 392 RU2 M PNTM == : E  
IR DUMMY CASSETTE FOR M MBL E  
CR IR 392 RU = X  
CR IR 392 RU2 PNTM = X : E  
HIGH CAP XMR : E  
CR IR 392 RU2 PNTM = ORT : E  
CR IR 392 RU2 M PNTM = ORT : E  
CR IR 392 RU2 M PNTM = W : E

2018-12-21

## Annex II 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. : 11-CEM-01-V

Applicable Product Units to  
Declaration of Conformity:

Serial No. \*\*\* 00272 or later (\*1,\*2)

Serial No. \*\*\* 32355 or later (\*3)

\*1 FCR PRIMA T,T2

\*2 FCR PRIMA T PLUS (for German dealers)

\*3 FCR PRIMA Tm