

## EC Declaration of Conformity

05-CEM-04-H

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 IP CASSETTE CC  
Model No.: —  
UMDNS: 20787  
Applicable Product Units: See Annex II  
Classification(MDD, Annex IX): Class I (Rule 1)

We herewith declare that the above mentioned product(s) meets the provisions of the following EC Council Directive and Standards.

Directive:  
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Standards:  
EN ISO13485:2003/AC:2009 Medical devices - Quality management systems - Requirements for regulatory purpose  
EN ISO14971:2009 Medical devices - Application of risk management to medical devices  
EN 62366:2008 Medical devices — Application of usability engineering to medical devices  
EN 1041:2008 Information supplied by the manufacturer of medical devices

Conformity Assessment Procedure: Annex VII

Place Kanagawa, JAPAN

Date 2012-01-19

  
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Yasuo Nagashima  
Senior Manager, Regulatory Affairs  
Quality Assurance Division  
Medical Systems Research & Development Center  
FUJIFILM Corporation

## Annex I to EC Declaration of Conformity

Quality Assurance Division  
Medical Systems Research & Development Center  
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. : 05-CEM-04-H

Material Description applicable to EC Declaration of Conformity :

FUJI IP CASSETTE CC :

IP CASS-CC BW PB 35.4×43CM 1 E
IP CASS-CC BW PB 35.4×43CM 1 =E
IP CASS-CC BW PB 35.4×43CM1 :E
IP CASS-CCB BW PB 35.4X43CM 1 E
IP CASS-CC BW 35.4×43CM 1 E
IP CASS-CC BW PB 35.4×35.4CM 1 E
IP CASS-CC BW PB 35.4×35.4CM 1 =E
IP CASS-CC BW PB35.4×35.4CM1:E
IP CASS-CCB BW PB 35.4X35.4CM 1 E
IP CASS-CC BW 35.4×35.4CM 1 E
IP CASS-CC BW PB 25.2×30.3CM 1 E
IP CASS-CC BW PB 25.2×30.3CM 1 =E
IP CASS-CC BW PB25.2×30.3CM1:E
IP CASS-CCB BW PB 25.2X30.3CM 1 E
IP CASS-CC BW 25.2×30.3CM 1 E
IP CASS-CC BW PB 20.1×25.2CM 1 E
IP CASS-CC BW PB 20.1×25.2CM 1 =E
IP CASS-CC BW PB20.1×25.2CM1 :E
IP CASS-CCB BW PB 20.1X25.2CM 1 E
IP CASS-CC BW 20.1×25.2CM 1 E
IP CASS-CC BW PB 24×30CM 1 E
IP CASS-CC BW PB 24×30CM 1 =E
IP CASS-CC BW PB 24×30CM 1 :E
IP CASS-CCB BW PB 24X30CM 1 E
IP CASS-CC BW 24×30CM 1 E
IP CASS-CC BW PB 18×24CM 1 E
IP CASS-CC BW PB 18×24CM 1 =E
IP CASS-CC BW PB 18×24CM 1 :E
IP CASS-CCB BW PB 18X24CM 1 E
IP CASS-CC BW 18×24CM 1 E
IP CASS-CC BW PB 15×30CM 1 E
IP CASS-CC BW 15×30CM 1 E

## Annex II to EC Declaration of Conformity

Quality Assurance Division  
Medical Systems Research & Development Center  
FUJIFILM Corporation

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EC Declaration of Conformity No. : 05-CEM-04-H

Description applicable to EC Declaration of Conformity :

FUJI IP CASSETTE CC :

Size:	window	Pb	Material Description	Applicable Product Units:
35.4 × 43cm	✓	✓	IP CASS-CC BW PB 35.4 × 43CM 1 E	Serial No. CCWSL17-100675 or later
35.4 × 43cm	✓	✓	IP CASS-CC BW PB 35.4 × 43CM 1 =E	Serial No. CCWSL17-203116 or later
35.4 × 43cm	✓	✓	IP CASS-CC BW PB 35.4 × 43CM 1 :E	Serial No. CCWSL17-3010949 or later
35.4 × 43cm	✓	✓	IP CASS-CCB BW PB 35.4X43CM 1 E	Serial No. CCWSL17-907823 or later
35.4 × 43cm	✓		IP CASS-CC BW 35.4 × 43CM 1 E	Serial No. CCWSO17-001246 or later
35.4 × 35.4cm	✓	✓	IP CASS-CC BW PB 35.4 × 35.4CM 1 E	Serial No. CCWSL14-016595 or later
35.4 × 35.4cm	✓	✓	IP CASS-CC BW PB 35.4 × 35.4CM 1 =E	Serial No. CCWSL14-200001 or later
35.4 × 35.4cm	✓	✓	IP CASS-CC BW PB35.4 × 35.4CM1:E	Serial No. CCWSL14-3003401 or later
35.4 × 35.4cm	✓	✓	IP CASS-CCB BW PB 35.4X35.4CM 1 E	Serial No. CCWSL14-900678 or later
35.4 × 35.4cm	✓		IP CASS-CC BW 35.4 × 35.4CM 1 E	Serial No. CCWSO14-000316 or later
25.2 × 30.3cm	✓	✓	IP CASS-CC BW PB 25.2 × 30.3CM 1 E	Serial No. CCWSL12-025487 or later
25.2 × 30.3cm	✓	✓	IP CASS-CC BW PB 25.2 × 30.3CM 1 =E	Serial No. CCWSL12-200001 or later
25.2 × 30.3cm	✓	✓	IP CASS-CC BW PB25.2 × 30.3CM1:E	Serial No. CCWSL12-3004462 or later
25.2 × 30.3cm	✓	✓	IP CASS-CCB BW PB 25.2X30.3CM 1 E	Serial No. CCWSL12-907503 or later
25.2 × 30.3cm	✓		IP CASS-CC BW 25.2 × 30.3CM 1 E	Serial No. CCWSO12-000230 or later
20.1 × 25.2cm	✓	✓	IP CASS-CC BW PB 20.1 × 25.2CM 1 E	Serial No. CCWSL08-014556 or later
20.1 × 25.2cm	✓	✓	IP CASS-CC BW PB 20.1 × 25.2CM 1 =E	Serial No. CCWSL08-200001 or later
20.1 × 25.2cm	✓	✓	IP CASS-CC BW PB20.1 × 25.2CM1 :E	Serial No. CCWSL08-3003351 or later
20.1 × 25.2cm	✓	✓	IP CASS-CCB BW PB 20.1X25.2CM 1 E	Serial No. CCWSL08-901853 or later
20.1 × 25.2cm	✓		IP CASS-CC BW 20.1 × 25.2CM 1 E	Serial No. CCWSO08-000256 or later
24x30cm	✓	✓	IP CASS-CC BW PB 24 × 30CM 1 E	Serial No. CCWSL30-017956 or later
24x30cm	✓	✓	IP CASS-CC BW PB 24 × 30CM 1 =E	Serial No. CCWSL30-201712 or later
24x30cm	✓	✓	IP CASS-CC BW PB 24 × 30CM 1 :E	Serial No. CCWSL30- 3005703 or later
24x30cm	✓	✓	IP CASS-CCB BW PB 24X30CM 1 E	Serial No. CCWSL30-901704 or later
24x30cm	✓		IP CASS-CC BW 24 × 30CM 1 E	Serial No. CCWSO30-001161 or later
18x24cm	✓	✓	IP CASS-CC BW PB 18 × 24CM 1 E	Serial No. CCWSL18-012682 or later
18x24cm	✓	✓	IP CASS-CC BW PB 18 × 24CM 1 =E	Serial No. CCWSL18-200013 or later
18x24cm	✓	✓	IP CASS-CC BW PB 18 × 24CM 1 :E	Serial No. CCWSL18-3003362 or later
18x24cm	✓	✓	IP CASS-CCB BW PB 18X24CM 1 E	Serial No. CCWSL18-901838 or later
18x24cm	✓		IP CASS-CC BW 18 × 24CM 1 E	Serial No. CCWSO18-001137 or later
15x30cm	✓	✓	IP CASS-CC BW PB 15 × 30CM 1 E	Serial No. CCWSL15-001869 or later
15x30cm	✓		IP CASS-CC BW 15 × 30CM 1 E	Serial No. CCWSO15-000366 or later