

EN

EU Declaration of Conformity

05-CEM-04-M

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:	4547410101000000000000438
Trade name:	FUJI IP CASSETTE CC
Model Number:	-
Applicable Products:	See Annex I
Classification (MDR, Annex VIII):	Class I (Rule 1)

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.

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 :

Function :

Naotake Mitsumori

General Manager,
Quality Assurance and Regulatory Affairs Division,
Medical Systems Business Division
FUJIFILM Corporation

Annex I to EU Declaration of Conformity

EU Declaration of Conformity No. : 05-CEM-04-L

Type (cm)	window	Pb	Material Description	Applicable Product Serial No.
35.4×43	V	V	IP CASS-CC BW PB 35.4×43CM 1 E	8015001 or later
35.4×43	V	V	IP CASS-CC BW PB 35.4×43CM1 :E	7053301 or later
35.4×43	V		IP CASS-CC BW 35.4×43CM 1 E	610001 or later
35.4×35.4	V	V	IP CASS-CC BW PB 35.4×35.4CM 1 E	8003001 or later
35.4×35.4	V	V	IP CASS-CC BW PB35.4×35.4CM1:E	7006051 or later
35.4×35.4	V		IP CASS-CC BW 35.4×35.4CM 1 E	610001 or later
25.2×30.3	V	V	IP CASS-CC BW PB 25.2×30.3CM 1 E	6100011 or later
25.2×30.3	V	V	IP CASS-CC BW PB25.2×30.3CM1:E	7015151 or later
25.2×30.3	V		IP CASS-CC BW 25.2×30.3CM 1 E	8001001 or later
20.1×25.2	V	V	IP CASS-CC BW PB 20.1×25.2CM 1 E	8001001 or later
20.1×25.2	V	V	IP CASS-CC BW PB20.1×25.2CM1 :E	7005751 or later
20.1×25.2	V		IP CASS-CC BW 20.1×25.2CM 1 E	610001 or later
24x30	V	V	IP CASS-CC BW PB 24×30CM 1 E	8009001 or later
24x30	V	V	IP CASS-CC BW PB 24×30CM 1 :E	7015041 or later
24x30	V		IP CASS-CC BW 24×30CM 1 :E	610001 or later
18x24	V	V	IP CASS-CC BW PB 18×24CM 1 E	8005001 or later
18x24	V	V	IP CASS-CC BW PB 18×24CM 1 :E	7007441 or later
18x24	V		IP CASS-CC BW 18×24CM 1 E	610001 or later
15x30	V	V	IP CASS-CC BW PB 15×30CM 1 E	60281 or later
15x30	V		IP CASS-CC BW 15×30CM 1 E	600701 or later
35.4×43		V	IP CASS-CC PB35.4X43 PRIMA :E	700006 or later
35.4×35.4		V	IP CASS-CC PB35.4X35.4 PRIMA:E	700006 or later
25.2×30.3		V	IP CASS-CC PB25.2X30.3 PRIMA:E	700006 or later
20.1×25.2		V	IP CASS-CC PB20.1X25.2 PRIMA:E	700006 or later
24x30		V	IP CASS-CC PB24X30 PRIMA :E	700006 or later
18x24		V	IP CASS-CC PB18X24 PRIMA :E	700006 or later