

EC Declaration of Conformity

06-CEM-11-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 DÜSSELDORF, GERMANY
Product(s): FUJI IMAGING PLATE
Model No.: ST-VI
UMDNS Code: 20764
GMDN Code: 44826
Applicable Product Units: See Annex
Classification (MDD, Annex IX): Class IIa (Rule 16)

We herewith declare in our own responsibility that the above mentioned product(s) meets the provisions of the following EC Council Directive(s) and standards.

Directive:
Medical Device Directive: 93/42/EEC and their Annexes

Standards:
EN ISO13485:2012/AC:2012
EN ISO14971:2012
EN 62366:2008

Notified Body: TÜV SÜD Product Service GmbH (Notified Body Number 0123)
Ridlerstr. 65, 80339 München, Germany
EC Certificate: G2 18 01 20011 045
Conformity Assessment Procedure: Annex V

Place and Date of issue

Kanagawa, JAPAN

2018-05-14

Signature :



Name : Naotake Mitsumori

Function: Senior Engineering Scientist
Quality Assurance and Regulatory Affairs Division
Medical Systems Business Division
FUJIFILM Corporation

Annex to EC Declaration of Conformity

General Quality Assurance & Regulatory Affairs Group
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 EC Declaration of Conformity.

Declaration Control No. : 06-CEM-11-H

Description applicable to Declaration of Conformity :

FUJI IMAGING PLATE ST-VI

Size:	Material Description	Applicable Product Units:
35.4×43.0cm	IP-6 ST 35.4X43CM 1 E	44988982 or later
35.4×35.4cm	IP-6 ST 35.4×35.4CM 1 E	
25.2×30.3cm	IP-6 ST 25.2×30.3CM 1 E	
23.8×29.8cm	IP-6 ST 24X30CM 1 E	
20.1×25.2cm	IP-6 ST 20.1X25.2CM 1 E	
17.8×23.8cm	IP-6 ST 18X24CM 1 E	
14.8×29.8cm	IP-6 ST 15X30CM 1 E	