FUJIFILM

FUJIFILM Corporation
26-30, NISHIAZABU 2-CHOME, MINATO-KU,
TOKYO 106-8620 JAPAN

Declaration of Conformity

DC-02162-H

Manufacturer:	FUJIFILM Corporation
Address:	26-30, Nishiazabu 2-chome, Minato-ku Tokyo 106-8620, JAPAN
Authorized Representative:	FUJIFILM Europe GmbH
Address:	Balcke-Duerr-Allee 6, 40882 Ratingen, Germany
Product:	Video Endoscope
Model No.:	ED-580XT
UMDNS:	17654 (Duodenoscopes, Video)
GMDN:	36112 (Flexible video duodenoscope, reusable)
Applicable Product Units:	Serial No. 7D127K001 or later
Classification (MDD, Annex IX):	Class IIa (Rule 5)

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

Directive:
Medical Device Directive: 93/42/EEC and their Annexes
RoHS Directive: 2011/65/EU, (EU) 2015/863

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

Place and Date of issue

Kanagawa, JAPAN

2022-04-01

Signature :

Name : Naotake Mitsumori
Function : General Manager,
Quality Assurance and Regulatory Affairs Division,
Medical Systems Business Division
FUJIFILM Corporation

Digitally signed by Bolea Petru
Date: 2023.07.18 09:05:12 EEST
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Location: Moldova