FUJIFILM

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

Declaration of Conformity

DC-02162-C

Manufacturer:	FUJIFILM Corporation
Address:	26-30, Nishiazabu 2-chome, Minato-ku, Tokyo 106-8620, JAPAN
Authorized Representative:	FUJIFILM Europe GmbH
Address:	Heesenstr. 31, 40549 Düsseldorf, GERMANY
Product:	Video Endoscope
Model No.:	ED-580XT
UMDNS:	17654 (Duodenoscopes, Video)
GMDN:	36112 (Flexible video duodenoscope)
Applicable Product Units:	Serial No. 2D127K001 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

Standards:

Harmonized Standards and not harmonized standards applicable to this product are:

EN ISO 13485:2012/ AC:2012
EN ISO 14971:2012
EN 60601-1:2006/ A1:2013
IEC 60601-1-6:2010/ A1:2013
EN 60601-1-2:2015
IEC 60601-2-18:2009
IEC 62366:2007/ A1:2014
EN ISO 17664:2004
EN 50581:2012
Not harmonized standards: ISO 8600-1:2015

Digitally signed by Bolea Petru
Date: 2021.08.20 15:55:23 EEST
Reason: MoldSign Signature
Location: Moldova

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

2018-10-24

Signature :

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