FUJIFILM

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

# Declaration of Conformity

DC-01939-D

| | |
|---|---|
| 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(s): | Video Endoscope |
| Model No.: | EB-580T |
| UMDNS: | 17662 ( Bronchoscopes, Flexible, Video ) |
| GMDN: | 17662 ( Flexible video bronchoscope, reusable ) |
| Applicable Product Lots: | Serial No. 4B090K001 or later |
| Classification (MDD, Annex IX): | Class IIa (Rule 5) |

We, FUJIFILM Corporation, herewith declare in our sole responsibility that the product(s) identified in this declaration conforms to the provisions of the following Directives 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 60601-2-18:2009
IEC 60601-1-6:2010+A1:2013
IEC 62366:2007+A1:2014
EN ISO 17664:2004
EN 60601-1-2:2015
EN 50581:2012
Not harmonized standards: ISO 8600-1:2015

EC Certificate for Directive 93/42/EEC: G1 17 07 20011 043
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

2018-08-27

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: 2024.03.26 14:23:55 EET
Reason: MoldSign Signature
Location: Moldova