FUJIFILM

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

Declaration of Conformity

DC-01909-I

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(s):	Video Endoscope
Model No.:	EC-760R-V/L
UMDNS:	17665 (Colonoscopes, Video)
GMDN:	36117 (Flexible video colonoscope, reusable)
Applicable Product Units:	Serial No. 8C729K001 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, (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 09:04:28 EEST
Reason: MoldSign Signature
Location: Moldova