OLYMPUS

EU-DECLARATION OF CONFORMITY

1. Manufacturer OLYMPUS MEDICAL SYSTEMS CORP.

2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan

Single Registration-No. N/A

2. Article(REF)No. / Article Name Please refer to Attachment 1

3. Product designation Please refer to Attachment 1

4. Serial or Lot No. range Please refer to Attachment 1

5. Product classification Please refer to Attachment 1

6. Authorized representatives in EU

Name Olympus Europa SE & Co. KG

Address Wendenstrasse 20, 20097 Hamburg, Germany *
*Until 31 May 2021 Wendenstrasse 14-18, 20097 Hamburg, Germany

Single Registration-No. TBA

7. Declaration

This declaration was made in sole responsibility of the manufacturer.
The stated product complies with the requirements of following European Directives and Regulations.

The declarations is based on: 93/42/EEC Annex II
2011/65/EU, (EU) 2015/863

8. Notified Body for MDD

Issued by TÜV Rheinland LGA Products GmbH

Address Tillystraße 2, 90431 Nürnberg, Germany

Registration-No. Registration-No.0197

Place, Date: Tokyo, 2021/6/24

Signature:

Director
Product Quality Assurance
Medical Quality Assurance and Regulatory Affairs
Yoshihito Horikawa

ATTACHMENT 1

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✦The EU-Declaration of Conformity is valid for the following articles:

Product designation	GMDN	EMDN (CND)	Article(REF)No. Article Name	Serial or Lot No. range	UDI-DI	Basic UDI-DI	Classification
EVIS EXERA III BRONCHOVIDEOSCOPE	17662	-	OLYMPUS BF-1TH190	From 2127137 to	N/A	N/A	Class IIa

✦Applied Standards [RoHS,RED,LVD,EMC]

[RoHS] EN IEC 63000 : 2018

Refer to the Essential Requirements Checklist for above mentioned product. [MDD]

✦Included items

Product designation	Article(REF)No. Article Name
CHANNEL CLEANING BRUSH	BW-15B
SINGLE USE COMBINATION CLEANING BRUSH	BW-411B
MOUTHPIECE	MA-651
STERILIZATION CAP	MAJ-1538
SUCTION VALVE	MAJ-207
SINGLE USE SUCTION VALSE	MAJ-209
SINGLE USE BIOPSY VALVE	MAJ-210
SUCTION CLEANING ADAPTER	MAJ-222
BIOPSY VALVE	MD-495
CHANNEL-OPENING CLEANING BRUSH	MH-507

✦Intended purpose:

This instrument is intended to be used with an Olympus video system center, light source,documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery.

✦Serial or Lot No.

Directive/Regulation	Re-issued DoC-Serial or Lot No. range Starting from	Ended at	New DoC-Serial or Lot No. range Starting from
93/42/EEC	2300001	-	-
2011/65/EU	2400906	2127136	-
2011/65/EU, (EU) 2015/863	-	-	2127137