

ATTACHMENT 1



◆ 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-H190	From 2128242 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 VALVE	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	2100001	-	-
2011/65/EU	2401016	2128241	-
2011/65/EU, (EU) 2015/863	-	-	2128242