

DECLARATION OF CONFORMITY (MDD)

OLYMPUS

1. Manufacturer Olympus Optical Co. Ltd.

2. Address 43-2, Hatagaya 2 Chome, Shibuya-ku, Tokyo, Japan

3. Model OLYMPUS TJF TYPE 140R

4. Name of product EVIS DUODENOVideoscope

5. Serial or Lot No. from 2810490 to

6. Classification Class ☒ IIa ☐ IIb

7. Authorized representatives in EU

☒ Name Olympus Opt.Co.(Europa) GmbH
Address Wendenstr.14-16 20097 Hamburg, Germanv

☐ Name Olympus Winter & Ibe GmbH
Address Kuehnstr.61 22045 Hamburg, Germany

☐ Name KeyMed (Medical & Industrial Equipment) Ltd.
Address KeyMed House, Stock Road Essex SS2 5QH, UK

We herewith declare that the above mentioned product complies with the requirements of EC Directive 93 / 42 / EEC (MDD).

This declaration is based on : MDD, Annex II

8. Certification of a quality system

Certificate No. HD 9510875 01
Issued by TÜV Rheinland Product Safety GmbH

Place 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan

Signature 

Name Osamu Komiya

Title Management Representative, Endoscope Division

Date 07. 05.1998

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ANNEX (RELATED ITEM LIST)

Page 1 of 1

The conformity in accordance with the EC directive 93/42/EEC (MDD) annex I is declared herewith also for the following related item/s that is/are provided together, as a part of the declaration of conformity of;

(model and name of the medical device)

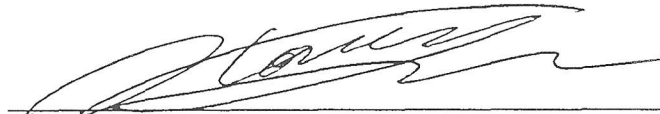
OLYMPUS TJF TYPE 140R

EVIS DUODENOVideoscope

Model and Name of the related item	Class	Serial or Lot No.		
MH-443(Suction Valve)	I	from	(*a)	to
MH-438(Air/Water Valve)	II a	from	(*a)	to
MB-358(Semi-disposable Biopsy Valve)	I	from	(*a>	to
MH-553(Water Resistance Cap)	I	from	(*a)	to
MH-507(Channel-opening Cleaning Brush)		from	(*a)	to
BW-20T(Channel Cleaning Brush)	I	from	(*a)	to
MH-856(Suction Cleaning Adapter)	I	from	(*a)	to
MH-944(Channel Plug)	I	from	(*a>	to
MH-946(Injection Tube)		from	(*a)	to
MH-948(AW Channel Cleaning Adapter)	I	from	(*a)	to
MB-142(Mouthpiece)	I	from	(*a)	to
MH-974(Washing Tube)	I	from	(*a)	to
MAJ-311(Distal Cover)	I	from	(*a)	to
		from		to

Note (*a) : The items manufactured on or after the signed date as shown below.

Signature



Name

Osamu Komiya

Title

Management Representative, Endoscope Division

Date

01.10.1998

[N-OIS D28001 Appendix 6]

Revision 1 : Oct. 1.1998