

**DECLARATION OF CONFORMITY(MDD)**

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1. Manufacturer Olympus Optical Co., Ltd.
2. Address 43-2, Hatagaya 2 Chome, Shibuya-ku, Tokyo, Japan
3. Model OLYMPUS GF TYPE UM160
4. Name of product EUS EXERA ULTRASONIC GASTROVIDEOSCOPE
5. Serial or Lot No. 1100031
6. Classification Class IIa


**7. Authorized representatives in EU**

- ☒ Name Olympus Opt.Co.(Europe) GmbH  
Address Wendenstr. 14-18 20097 Hamburg, Germany
- ☐ 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**

- Issued by TUV Rheinland Product Safety GmbH
- Place 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
- Signature 
- Name Tatsuya Yamaguchi
- Title Management Representative, Medical Systems Group
- Date 8. 2. 2002

**DECLARATION OF CONFORMITY(MDD)****ANNEX (RELATED ITEM LIST)**

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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 GF TYPE UM160 EUS EXERA ULTRASONIC GASTROVIDEOSCOPE**

Model and Name of the related item	Class	Serial or Lot No.
MH-303(Balloon2)	I	from 97.11 to
BW-20T(Channel Cleaning Brush)	I	from 98/10/01 to
BW-7L(Channel Cleaning Brush)	I	from 98/10/01 to
MH-507(Channel-opening Cleaning Brush)	I	from 98/10/01 to
MB-146(Silicon Oil)	I	from 98/10/01 to
MAJ-952(Water-resisitant Plug)	I	from 2002.2 to
MH-553(Water Resistance Cap)	I	from 98/10/01 to
MAJ-621(Channel Plug)	I	from 98/10/01 to
MAJ-629(Air/Water Channel Cleaning Adapter)	I	from 98/10/01 to
MD-754(Air/Water Valve)	IIa	from 98/10/01 to
MD-755(Suction Valve)	I	from 98/10/01 to
MD-688(Balloon Applicator)	I	from 98/10/01 to
MB-142(Mouthpiece)	I	from 98/10/01 to
MH-946(Injection Tube)	I	from 98/10/01 to
MH-856(Suction Cleaning Adapter)	I	from 98/10/01 to

Signature



Name

Tatsuya Yamaguchi

Title

Management Representative, Medical Systems Group

Date

8. 2. 2002