

DECLARATION OF CONFORMITY (MDD)

OLYMPUS

1. Manufacturer Olympus Optical Co. Ltd.
2. Address 43-2, Hatagaya 2 Chome, Shibuya-ku, Tokyo, Japan
3. Model GIF-Q160
4. Name of product EVIS EXERA GASTROINTESTINAL VIDEOSCOPE
5. Serial or Lot No. from 2000001 to
6. Classification Class ☒ IIa ☐ IIb

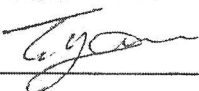
7. Authorized representatives in EU

- ☒ Name Olympus Opt.Co.(Europa) GmbH
Address Wendenstr.14-16 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

- Certificate No. HD 9510875 01
- Issued by TÜV Rheinland Product Safety GmbH
- Place 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
- Signature 
- Name Tatsuya Yamaguchi
- Title Management Representative, Endoscope Division
- Date 08. 03. 2000

[N-OIS D28001 Appendix 3]

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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)

GIF-Q160

EVIS EXERA GASTROINTESTINAL VIDEOSCOPE

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

Note (*a) : The items manufactured on or after 1. Oct. 1998.

Signature



Name

Tatsuya Yamaguchi

Title

Management Representative, Endoscope Division

Date

08. 03. 2000

[N-OIS D28001 Appendix 6]