

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 GIF TYPE 2T20

4. Name of product OES GASTROINTENSTINAL FIBERSCOPE

5. Serial or Lot No. from 2811016 to

6. Classification Class Ha 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

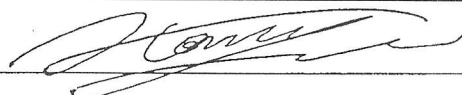
We herewith declare that the above mentioned product complies with the requirements of EC Directive 93 / 42 / EEC (MDD).

This declaration is based on : MDD, Annex II

8. Certification of a quality system

Certificate No. HD 9510875 01 / Report No. E 9560434 E 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 04. 03.1998

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ANNEX (RELATED ITEM LIST)

OLYMPUS

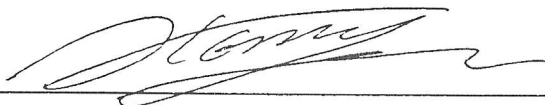
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The conformity in accordance with the EC directive 93/42/EEC (MDD) annex I is declared herewith also for the following related item/s that is/are provided together, as a part of the declaration of conformity of;

(model and name of the medical device)	OLYMPUS GIF TYPE 2T20 OES GASTROINTESTINAL FIBERSCOPE		
Model and Name of the related item	Class	Serial or Lot No.	
MH-507(Channel-opening Cleaning Brush)	I	from	(*a) to
BW-20T(Channel Cleaning Brush)	I	from	(*a) to
MB-107(A/W Channel Cleaning Adapter)	I	from	(*a) to
MB-146(Lubricant)	I	from	(*a) to
MB-156(ETO Cap)	I	from	(*a) to
MB-19(Channel Cleaning Adapter)	I	from	(*a) to
MB-358(Semi-disposable Biopsy Valve)	I	from	(*a) to
MB-196(Air/Water Valve)	II a	from	(*a) to
MB-197(Suction Valve)	I	from	(*a) to
CW-3(All-Channel Irrigator)	I	from	(*a) to
MA-474(Mouthpiece)		from	(*a) to
MB-142(Mouthpiece)	I	from	(*a) to
MD-105(Forceps/Irrigation Plug)		from	(*a) to
MB-10S(Elevator-wire-Channel Cleaning Tube)	I	from	(*a) to
MB-531(Suction Switchover Lever)		from	(*a) to

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

Signature



Name

Osamu Komiya

Title

Management Representative, Endoscope Division

Date

07.01.1999

[N-OIS D28001 Appendix 6]

Revision 2 : Jan. 7.1999