

DECLARATION OF CONFORMITY(MDD)

1. **Manufacturer** OLYMPUS CORPORATION

2. **Address** 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan

3. **Model** UHI-2

4. **Name of product** HIGH FLOW INSUFFLATION UNIT

5. **Serial or Lot No.** from 7800001 to 7011227
from 1011228 to

6. **Classification** Class IIa

7. **Authorized representatives in EU**

- Name** Olympus Europa 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,Southend-on Sea, 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 Kazuma Kawashima

Title Management Representative, Medical Systems Group

Date 2004/01/30(yyyy.mm.dd)

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OLYMPUS

ANNEX (RELATED ITEM LIST)

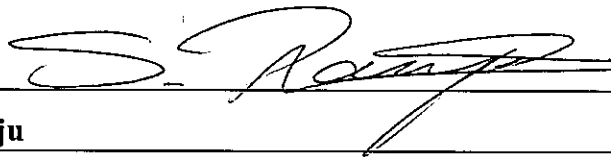
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The conformity in accordance with the EC directive 93/42/EEC (MDD) annex I is declared herewith also for the following related item/s that is/are provided together, as a part of the declaration of conformity of ;

(model and name of the medical device) **UHI-2 HIGH FLOW INSUFFLATION UNIT**

Model and Name of the related item	Class	Serial or Lot No.
MAJ-590(INSUFFLATION TUBE)	IIa	from 98/10/01 to 07/10/31 from 07/11/01 to from 09/04/01 to
MAJ-591(SUCTION TUBE)	I	from 98/10/01 to 07/10/31 from 07/11/01 to from 09/04/01 to
MAJ-622(Hose For Cylinder(PIN))	IIa	from 98/10/01 to
MAJ-623(Hose For Cylinder(DIN))	IIa	from 98/10/01 to
MAJ-624(Hose For Cylinder(ISO))	IIa	from 98/10/01 to
MAJ-625(Hose For Cylinder(US))	IIa	from 98/10/01 to
MAJ-626(Adaptor For Medical Gas Pipeline (NIST))	IIa	from 98/10/01 to
MAJ-627(Adaptor For Medical Gas Pipeline (DISS))	IIa	from 98/10/01 to
MH-317(FOOT SWITCH)	I	from 98/10/01 to 07/10/31 from 7704501 to from E900002 to
MH-397(INSUFFLATION TUBE)	IIa	from 98/10/01 to 07/10/31 from 07/12/21 to

Signature



Name

Seiya Raiju

Title

General Manager,
Regulatory Affairs & Quality Assurance Department

Date

2010/05/20(yyyy.mm.dd)

[N-OIS D28001 Appendix 6]
Revision 1 :2010/05/20 (yyyy.mm.dd)