

DECLARATION OF CONFORMITY(MDD)

1. Manufacturer OLYMPUS MEDICAL SYSTEMS CORP.
2. Address 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
3. Model OBCU
4. Name of product BALLOON CONTROL UNIT
5. Serial or Lot No. from 7700051 to
6. Classification Class IIa

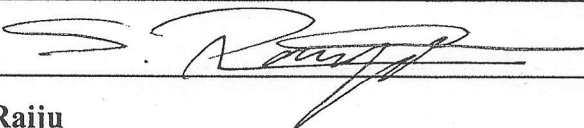
7. Authorized representatives in EU

- Name Olympus Medical Systems 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 (0197)

Place 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
Signature 
Name Seiya Raiju
Title General Manager,
Regulatory Affairs & Quality Assurance Department
Date 2007/05/30(yyyy.mm.dd)

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ANNEX (RELATED ITEM LIST)

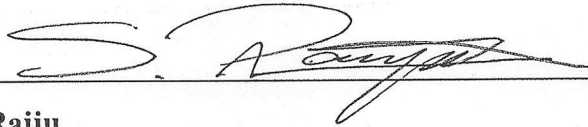
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The conformity in accordance with the EC directive 93/42/EEC (MDD) annex I is declared herewith also for the following related item/s that is/are provided together, as a part of the declaration of conformity of ;

(model and name of the medical device) **OBCU BALLOON CONTROL UNIT**

Model and Name of the related item	Class	Serial or Lot No.
MAJ-1726(OBCU REMOTE CONTROLLER)	I	from 7700052 to
MAJ-1727(RESERVOIR TANK)	IIa	from May/30/2007 to
MAJ-1750(FOOT HOLDER)	I	from May/30/2007 to
MAJ-1751(SPARE FUSE)	I	from May/30/2007 to

Signature



Name

Seiya Raiju

Title

General Manager,
Regulatory Affairs & Quality Assurance Department

Date

2007/05/30(yyyy.mm.dd)

[N-OIS D28001 Appendix 6]

DECLARATION OF CONFORMITY(MDD)

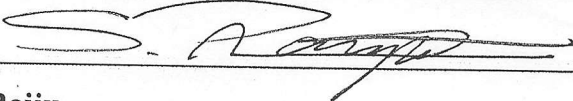
1. Manufacturer OLYMPUS MEDICAL SYSTEMS CORP.
2. Address 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
3. Model ST-SB1
4. Name of product SINGLE USE SPLINTING TUBE
5. Serial or Lot No. from 1700002 to
6. Classification Class IIa
7. Authorized representatives in EU
- Name Olympus Medical Systems Europa 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

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