KeyMed (Medical & Industrial Equipment) Ltd.
KeyMed House, Stock Road, Southend-on-Sea, Essex SS2 5QH, UK
Telex: 995283, Facsimile: (01702) 465677, Telephone: (01702) 616333

Registered to EN ISO 9001, EN 46001 and Annex II of the Medical Device Directive. Certificate Nos FM 20993 and EC 0424.

DECLARATION OF CONFORMITY to Annex II of the Medical Device Directive, Ref: 93/42/EEC

Declaration Ref. No: DC/MA1109/033

Device Part No: 7266189/7266146

Description: SSU-2 Suction Pump

Notified Body Ref. No: 086

Device or Accessory? Device

Classification: Class IIa

Declaration:

This device/accessory has been designed, manufactured and inspected under application of the quality system approved to Annex II of Directive 93/42/EEC and meets the provisions of the Directive which apply to it.

Checklist reference ER 003 **Issue** 3 **dated** 1/5/98 **refers.**

Applicability:

On the basis of an appropriate review of any approved changes to the design of this device/accessory, the above referenced checklist applies to all devices/accessories with the above part no. identified by the following range of serial numbers and/or batch (lot) numbers:

Serial number range: From 98 05210 **to** _____

Batch number range: From _____ **to** _____

Initials and date of entry of final s/no or b/no data:

If the "to" numbers above are not entered, it indicates that current production of the device/accessory is covered by this declaration.

Should any approved changes to the design of the product affect the validity of information contained in the above referenced checklist, the checklist will be upissued and reverification that the device/accessory meets the requirements of Directive 93/42/EEC carried out and recorded on a superseding declaration. At the time of implemetation of the design change into the product, the serial/batch numbers of the last items manufactured to the previous design will be entered in the "to" section above, thus recording the full range of items to which this declaration refers.

I declare that on the basis of the above information, the given numbers of the device/accessory detailed above are in compliance with the requirements of Annex II of Directive 93/42/EEC. This declaration will be kept at the disposal of the competent authorities for a minimum of five years after the last sale of the above device/accessory.

Signed: _____ *Quality Manager* *Date:* 8 June 1998

Name: M Skelt

Empowered to sign on behalf of KeyMed (Medical & Industrial Equipment) Ltd.

DECLARATION OF CONFORMITY(MDD)

OLYMPUS

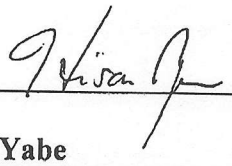
1. Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.
2. Address	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
3. Model	OEV191H
4. Name of product	HIGH DEFINITION LCD MONITOR
5. Serial or Lot No.	from SN7500024 to
6. Classification	Class I

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 VII

Place	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
Signature	
Name	Hisao Yabe
Title	Management Representative, Medical Systems Group
Date	2005/04/06(yyyy.mm.dd)

[N-OIS D28001 Appendix 2]

OLYMPUS

DECLARATION OF CONFORMITY(MDD)

ANNEX (RELATED ITEM LIST)

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

(model and name of the medical device) OEV191H HIGH DEFINITION LCD MONITOR

Model and Name of the related item	Class	Serial or Lot No.
MAJ-1431(HD/SD SDI ADAPTER)	I	from SN7500010 to

Signature

Name Hisao Yabe

Title Management Representative, Medical Systems Group

Date 2005/04/06(yyyy.mm.dd)

[N-OIS D28001 Appendix 6]

OLYMPUS

DECLARATION OF CONFORMITY(MDD)

1. Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2. Address: 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
3. Model: OLYMPUS GIF TYPE FQ260Z
4. Name of product: EVIS LUCERA GASTROINTESTINAL VIDEOSCOPE
5. Serial or Lot No.: from 2600021 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: Hisao Yabe

Title: General Manager,
Regulatory Affairs & Quality Assurance Department

Date: 2006/11/09(yyyy.mm.dd)

[N-OIS D28001 Appendix 3]

OLYMPUS

DECLARATION OF CONFORMITY(MDD)

1. Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.
2. Address	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
3. Model	OLYMPUS CV-260SL
4. Name of product	EVIS LUCERA VIDEO SYSTEM CENTER
5. Serial or Lot No.	from 7600082 to
6. Classification	Class I

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 VII

Place	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
Signature	
Name	Hisao Yabe
Title	General Manager, Regulatory Affairs & Quality Assurance Department
Date	2006/06/07(yyyy.mm.dd)

[N-OIS D28001 Appendix 2]

DECLARATION OF CONFORMITY(MDD)

OLYMPUS

ANNEX (RELATED ITEM LIST)

The conformity in accordance with the EC directive 93/42/EEC (MDD) annex I is declared herewith also for the follwing 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 CV-260SL EVIS LUCERA VIDEO SYSTEM CENTER

Model and Name of the related item	Class	Serial or Lot No.
MAJ-1587(HDTV MONITOR CABLE)	I	from 7 June 2006 to
MAJ-1536(KEYBOARD)	I	from 7 June 2006 to

Signature

Name Hisao Yabe

Title General Manager,
Regulatory Affairs & Quality Assurance Department

Date 2006/06/07(yyyy.mm.dd)

[N-OIS D28001 Appendix 6]

OLYMPUS

DECLARATION OF CONFORMITY(MDD)

1. Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.
2. Address	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
3. Model	OLYMPUS CLV-260SL
4. Name of product	EVIS LUCERA XENON LIGHT SOURCE
5. Serial or Lot No.	from 7600074 to
6. Classification	Class IIa

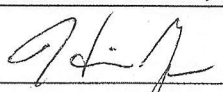
7. Authorized representatives in EU

■	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	Hisao Yabe
Title	General Manager, Regulatory Affairs & Quality Assurance Department
Date	2006/06/07(yyyy.mm.dd)

[N-OIS D28001 Appendix 3]

OLYMPUS

DECLARATION OF CONFORMITY(MDD)

ANNEX (RELATED ITEM LIST)

The conformity in accordance with the EC directive 93/42/EEC (MDD) annex I
is declared herewith also for the follwing 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 CLV-260SL EVIS LUCERA XENON LIGHT SOURCE

Model and Name of the related item	Class	Serial or Lot No.
MAJ-1530(LIGHT SOURCE CABLE)	I	from 7 June 2006 to

Signature

Name Hisao Yabe

Title General Manager,
Regulatory Affairs & Quality Assurance Department

Date 2006/06/07(yyyy.mm.dd)

[N-OIS D28001 Appendix 6]