### Key/Ne:

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.

Device or Accessory? Device Classification: Class IIa  Declaration:  This device/accessory has been designed, manufactured and inspected under application of the qualified system approved to Annex II of Directive 93/42/EEC and meets the provisions of the Directive which application it.  Checklist reference ER 003 Issue 3 dated 1/5/98 refers 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 Initials and date of end of this device/accessory of the "to" numbers above are not entered, it indicates that current production of the device/accessory covered by this declaration.  Should any approved changes to the design of the product affect the validity of information contained the above referenced checklist, the checklist will be upissued and reverification that the device/accessory covered by this declaration of the design change into the product, the serial/batch numbers of the last item 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.  declare that on the basis of the above information, the given numbers of the device/accessory detailed above are compliance with the requirements of Annex II of Directive 93/42/EEC. This declaration will be kept at the disposal recompliance with the requirements of Annex II of Directive 93/42/EEC. This declaration will be kept at the disposal recompliance with the requirements of Annex II of Directive 93/42/EEC. This declaration will be kept at the disposal recompletent authorities for a minimum of five years after the last sale of the above device/accessory.		Device Part No:		7266189/7266146			
Declaration:  This device/accessory has been designed, manufactured and inspected under application of the quasystem approved to Annex II of Directive 93/42/EEC and meets the provisions of the Directive which applicate to it.  Checklist reference			Description:		SS	U-2 Suction	on Pump
Declaration:  This device/accessory has been designed, manufactured and inspected under application of the qua system approved to Annex II of Directive 93/42/EEC and meets the provisions of the Directive which application it.  Checklist reference	Notified Body Ref. No: _	086					
This device/accessory has been designed, manufactured and inspected under application of the quasystem approved to Annex II of Directive 93/42/EEC and meets the provisions of the Directive which application to it.  Checklist reference	Device or Accessory? _	Device	Classification	Classification:		Class IIa	
Applicability:  On the basis of an appropriate review of any approved changes to the design of this device/accessory, to 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 Initials and date of both and the "to" numbers above are not entered, it indicates that current production of the device/accessory covered by this declaration.  Should any approved changes to the design of the product affect the validity of information contained the above referenced checklist, the checklist will be upissued and reverification that the device/accessor meets the requirements of Directive 93/42/EEC carried out and recorded on a superseding declaration. In the time of implementation of the design change into the product, the serial/batch numbers of the last item 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.  declare that on the basis of the above information, the given numbers of the device/accessory detailed above are compliance with the requirements of Annex II of Directive 93/42/EEC. This declaration will be kept at the disposative compliance with the requirements of Annex II of Directive 93/42/EEC. This declaration will be kept at the disposative completent authorities for a minimum of five years after the last sale of the above device/accessory.	Declaration:						
Applicability:  On the basis of an appropriate review of any approved changes to the design of this device/accessory, to above referenced checklist applies to all devices/accessories with the above part no. identified by to following range of serial numbers and/or batch (lot) numbers:  Serial number range: From	system approved to Anni	as been designed, i ex II of Directive 93/	manufactured and in 42/EEC and meets the	nspected ne provisi	under appl ons of the	ication of Directive w	the quality hich apply
Applicability:  On the basis of an appropriate review of any approved changes to the design of this device/accessory, to above referenced checklist applies to all devices/accessories with the above part no. identified by to following range of serial numbers and/or batch (lot) numbers:  Serial number range: From					_ dated	1/5/98	_ refers.
If the "to" numbers above are not entered, it indicates that current production of the device/accessory covered by this declaration.  Should any approved changes to the design of the product affect the validity of information contained the above referenced checklist, the checklist will be upissued and reverification that the device/accesso meets the requirements of Directive 93/42/EEC carried out and recorded on a superseding declaration. At the time of implementation of the design change into the product, the serial/batch numbers of the last item 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.  declare that on the basis of the above information, the given numbers of the device/accessory detailed above are competent authorities for a minimum of five years after the last sale of the above device/accessory.	Applicability:  On the basis of an appropabove referenced checkle following range of serial	priate review of any sist applies to all denumbers and/or bate	approved changes to evices/accessories v ch (lot) numbers:	o the desi with the a	bove part	no. identifi	ied by the
If the "to" numbers above are not entered, it indicates that current production of the device/accessory covered by this declaration.  Should any approved changes to the design of the product affect the validity of information contained the above referenced checklist, the checklist will be upissued and reverification that the device/accesso meets the requirements of Directive 93/42/EEC carried out and recorded on a superseding declaration. In the time of implementation of the design change into the product, the serial/batch numbers of the last item 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.  declare that on the basis of the above information, the given numbers of the device/accessory detailed above are compliance with the requirements of Annex II of Directive 93/42/EEC. This declaration will be kept at the disposation of the completent authorities for a minimum of five years after the last sale of the above device/accessory.					<b>P</b>	nitials and di of final s/no o	ite of entry b/no data:
Should any approved changes to the design of the product affect the validity of information contained the above referenced checklist, the checklist will be upissued and reverification that the device/accesso meets the requirements of Directive 93/42/EEC carried out and recorded on a superseding declaration. At the time of implementation of the design change into the product, the serial/batch numbers of the last item 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.  declare that on the basis of the above information, the given numbers of the device/accessory detailed above are compliance with the requirements of Annex II of Directive 93/42/EEC. This declaration will be kept at the disposative competent authorities for a minimum of five years after the last sale of the above device/accessory.	Batch number range: Fr	om	to				
the above referenced checklist, the checklist will be upissued and reverification that the device/accesso meets the requirements of Directive 93/42/EEC carried out and recorded on a superseding declaration. It the time of implementation of the design change into the product, the serial/batch numbers of the last item 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.  declare that on the basis of the above information, the given numbers of the device/accessory detailed above are compliance with the requirements of Annex II of Directive 93/42/EEC. This declaration will be kept at the disposance competent authorities for a minimum of five years after the last sale of the above device/accessory.	If the "to" numbers above covered by this declaration	e are not entered, it on.	indicates that curre	nt produc	ction of the	device/ac	essory is
compliance with the requirements of Annex II of Directive 93/42/EEC. This declaration will be kept at the disposate the competent authorities for a minimum of five years after the last sale of the above device/accessory.	the above referenced che meets the requirements of the time of implementation manufactured to the previ	cklist, the checklist f Directive 93/42/EE of the design chanç ous design will be e	will be upissued and C carried out and re- ge into the product, t	d reverific corded or the serial/l	ation that t n a superse batch numb	he device/a ding decla pers of the	ration. At last items
Signed: Quality Manager Date: 8 June 1998	compliance with the requiren	nents of Annex II of D	irective 93/42/EEC. T	This declar	ation will be	kept at the	above are in disposal of
	Signed:		_ Quality Manager	Date	e:8	June 1998	3

**DECLARATION OF CONFORMITY** 

DC/MA1109/033

to Annex II of the Medical Device

Directive, Ref: 93/42/EEC

Declaration Ref. No:

# **OLYMPUS**

## DECLARATION OF CONFORMITY(MDD)

turer	OLYMPUS MEDICAL SYSTEMS CORP.		
	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan		
	OEV191H		
product	HIGH DEFINITION LCD MONITOR		
Lot No.	from SN7500024 to		
tion	Class I		
d represent	atives 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 Address	KeyMed (Medical & Industrial Equipment) Ltd.  KeyMed House,Stock Road,Southend-on Sea, Essex SS2 5QH,  UK		
declare that 93 / 42 / EE	t the above mentioned product complies with the requirements of C (MDD).		
ion is based	on: MDD, Annex VII		
5			
	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan		
	- Thisa A		
	Hisao Yabe		
	Management Representative, Medical Systems Group		
	2005/04/06(yyyy.mm.dd)		
	product Lot No. tion d represent Name Address Name Address Name Address		



#### ANNEX (RELATED ITEM LIST)

page 1 of 1

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) OEV191H H	IGH DEFINITION LCD	MONITOR	
Model and Name of the	related item	Class	Serial or Lot No.	
MAJ-1431(HD/SD SD	I ADAPTER)	1	from SN7500010 to	
Signature	Though			
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 repres	entatives 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 Address  We herewith declare	KeyMed (Medical & Industrial Equipment) Ltd.  KeyMed House,Stock Road,Southend-on Sea, Essex SS2 5QH, UK  that the above mentioned product complies with the requirements of EC		
Directive 93 / 42 / EE			
This declaration is ba	ased 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	9 Life		
Name	Hisao Yabe		
Title	General Manager, Regulatory Affairs & Quality Assurance Department		
Date	<b>2006/11/09</b> (yyyy.mm.dd)		

[N-OIS D28001 Appendix 3]

## **OLYMPUS**

### DECLARATION OF CONFORMITY(MDD)

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 represen	itatives 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
Directive 93 / 42 / EEC	nat the above mentioned product complies with the requirements of EC (MDD).  ed on: MDD, Annex VII
Place	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
Signature	9/1
Name	Hisao Yabe
Title	General Manager, Regulatory Affairs & Quality Assurance Department
Date	2006/06/07(yyyy mm dd)

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

[N-OIS D28001 Appendix 2]



#### ANNEX (RELATED ITEM LIST)

page 1 of 1

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) CENTER

OLYMPUS CV-260SL EVIS LUCERA VIDEO SYSTEM

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)	<u>I</u>	from 7 June 2006 to
Signature 74		
Name Hisao Yabe		and a second of the second

Title General Manager,

Regulatory Affairs & Quality Assurance Department

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

[N-OIS D28001 Appendix 6]



1. Manufa	acturer	OLYMPUS MEDICAL SYSTEMS CORP.		
2. Address	S	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan		
3. Model		OLYMPUS CLV-260SL		
4. Name o	f product	EVIS LUCERA XENON LIGHT SOURCE		
5. Serial o	r Lot No.	from 7600074 to		
6. Classifi	cation	Class IIa		
7. Authori	zed representa	atives 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 Address	KeyMed (Medical & Industrial Equipment) Ltd.  KeyMed House,Stock Road,Southend-on Sea, Essex SS2 5QH, UK		
	th declare that 3 / 42 / EEC (I	t the above mentioned product complies with the requirements of EC MDD).		
This declaration is based on: MDD, Annex II				
8. Certification	ation of a qual	ity system: Issued by TUV Rheinland Product Safety GmbH (0197)		
Place		2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan		
Signature		941		
Name		Hisao Yabe		
Title		General Manager, Regulatory Affairs & Quality Assurance Department		
Date		2006/06/07(yyyy.mm.dd)		

[N-OIS D28001 Appendix 3]



#### ANNEX (RELATED ITEM LIST)

page 1 of 1

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;

SOURCE

(model and name of the medical device) OLYMPUS CLV-260SL EVIS LUCERA XENON LIGHT

Model and Name	of the related item	Class	Serial or Lot No.	
MAJ-1530(LIGHT SOURCE CABLE)		<u> </u>	from 7 June 2006 to	
Signature Name	Hisao Yabe			
Title	General Manager, Regulatory Affairs & Qua	General Manager, Regulatory Affairs & Quality Assurance Department		
Date	2006/06/07(yyyy.mm.dd)		[N-OIS D28001 Appendix 6]	