DECLARATION OF CONFORMITY(MDD)

OLYMPUS

1. Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.
2. Address	2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507 Japan
3. Model	B-V232P-A, B-V232P-B, B-V432P-A, B-V432P-B, B-V242Q-A, B-V242Q-B, B-V442Q-A, B-V442Q-B
4. Name of product	Single Use 3-Lumen Extraction Balloon V
5. Serial or Lot No.	from 09K to , from 49V to
6. Classification	Class I (Sterile)

7. Authorized representative in EU

Name	Olympus Europa SE & Co. KG
Address	Wendenstr. 14-18 20097 Hamburg, Germany

We hereby declare that the above mentioned product complies with the requirements of EC Directive 93/42/EEC(MDD)under the sole responsibility as a legal manufacturer. This Declaration of Conformity is valid in manufactured devices with the above Serial/Lot number.

This declaration is based on : MDD, Annex V and Annex VII

8. Notified Body Approval

Issued by	TÜV Rheinland LGA Products GmbH (0197)
Address	Tillystrasse 2, D-90431 Nürnberg, Germany

9. Applied Standards — Refer to the Essential Requirements Checklist for above mentioned product.

Place	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
Signature	
Name	Hiroki Moriyama
Title	General Manager Regulatory Affairs & Quality Assurance Department Quality & Environment Division
Date	2015/02/23

Revision 1
[N-OIS D28001 Appendix 7]

TERUMO

No.DOC-DQ010- 0807

Rev.08

DECLARATION OF CONFORMITY

We, TERUMO CORPORATION
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan

being the manufacturer of:

Single Use Guidewire

Product : Guide Wire for Endoscopy
(Model: G-240-2527S, G-240-2527A, G-240-2545S, G-240-2545A
G-240-3527S, G-240-3527A, G-240-3545S, G-240-3545A
G-260-2527S, G-260-2527A, G-260-2545S, G-260-2545A
G-260-3527S, G-260-3527A, G-260-3545S, G-260-3545A)

declare that the above products of **Class IIa** are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 2 and 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60121893 0001), Tillystraße 2, 90431 Nürnberg Germany, as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :
OLYMPUS EUROPA SE & CO. KG
Wendenstrasse 14-18, 20097 Hamburg, Germany

Object of the declaration: see appendix A

Tokyo, August 30, 2017
(place and date of issue)

Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

Appendix A - List of Code Number Structure

□ □ – □ □ □ □ □ □ □ □ □ □

1 2 3 4 5 6 7 8 9 10 11 12

Character number	Denotation	
1-2	Product name	**OL** : For Olympus Corp.
3	Destination	— : for domestic / export
4	Shaft	**X** : Cross marking type
5	Tip configuration	**S** : Straight, **A** : Angled
6-7	Diameter type (for combination device)	**25** : 0.025", **35** : 0.035"
8-9	Overall length	**27** : 2700mm, **45** : 4500mm
10	Flexible part at distal end	**3** : 3 taper, **5** : 5 taper
11	Package materials	Blank: for domestic, **M**: for export
12	Reserved	

DECLARATION OF CONFORMITY(MDD)

OLYMPUS

1. Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.
2. Address	2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507 Japan
3. Model	HX-610-090, HX-610-135, HX-610-090L, HX-610-090S, HX-610-135S, HX-610-090SC
4. Name of product	Clip, Long Clip, Short Clip, Colored Short Clip
5. Serial or Lot No.	from 4ZK to
6. Classification	Class IIa

7. Authorized representatives in EU

■ Name	Olympus Europa Holding GmbH
Address	Wendenstr. 14-18 20097 Hamburg,Germany

We herewith declare that the above mentioned product complies with the requirements of EC Directive 93/42/EEC(MDD) as amended by 2007/47/EC.

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	2010/03/04(yyyy.mm.dd)

[N-OIS D28001 Appendix 3]
Revision 1 :2010/03/04 (yyyy.mm.dd)

DECLARATION OF CONFORMITY(MDD)

OLYMPUS

1. Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2. Address: 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507 Japan
3. Model: HX-810LR,HX-810QR,HX-810UR
4. Name of product: Single Use Reloadable Clip Applicator
5. Serial or Lot No.: From 71K to
6. Classification: Class I Sterile
7. Authorized representative in EU

   Name: Olympus Europa SE & Co. KG
   Address: Wendenstr. 14-18 20097 Hamburg, Germany

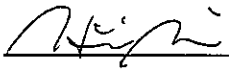
We hereby declare that the above mentioned product complies with the requirements of EC Directive 93/42/EEC(MDD)under the sole responsibility as a legal manufacturer. This Declaration of Conformity is valid in manufactured devices with the above Serial/Lot number.

This declaration is based on : MDD, Annex V and Annex VII

8. Applied Standards: Refer to the Essential Requirements Checklist for above mentioned product.
9. Notified Body Approval

   Issued by: TÜV Rheinland LGA Products GmbH (0197)
   Address: Tillystrasse 2, D-90431 Nürnberg, Germany

Place: 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507 Japan

Signature: 

Name: Hiroki Moriyama

Title: General Manager
Medical Quality Department
Medical Quality & Regulatory Division

Date: 2017/1/31

Revision 0
[N-OIS D28001 Appendix 7]

DECLARATION OF CONFORMITY(MDD)

OLYMPUS

1. Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.

2. Address: 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507 Japan

3. Model: K-005,K-006,K-007,K-008,K-009

4. Name of product: DISPOSABLE EMR KIT

5. Serial or Lot No.: K-005:from 1XK to 97K,from 97K to 99K,from 98I to 99I,from 99K to 23K,from 99I to23I,from 23K to,from 23I to, K-006,K-007,K-008,K-009:from 1XK to 97K,from 97K to 04K,from 98I to 04I, from 04K to 23K,from 04I to 23I, from 23K to,from 23I to,

6. Classification: Class IIb

7. Authorized representative in EU

   Name: Olympus Europa Holding GmbH

   Address: Wendenstr. 14-18 20097 Hamburg, Germany

We hereby declare that the above mentioned product complies with the requirements of EC Directive 93/42/EEC(MDD)under the sole responsibility as a legal manufacturer. This Declaration of Conformity is valid in manufactured devices with the above Serial/Lot number.

This declaration is based on : MDD, Annex II.3

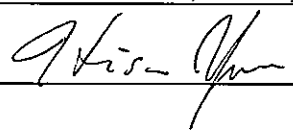
8. Notified Body Approval

   Issued by: TÜV Rheinland LGA Products GmbH (0197)

   Address: Tillystrasse 2, D-90431 Nürnberg, Germany

9. Applied Standards: Refer to the Essential Requirements Checklist for above mentioned product.

Place: 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan

Signature: 

Name: Hisao Yabe

Title: Division Manager,
Quality & Environment Division

Date: 2012/03/28

DECLARATION OF CONFORMITY(MDD)

OLYMPUS

1. Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.
2. Address	2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507 Japan
3. Model	KD-655L/Q/U
4. Name of product	Single Use Electrosurgical Knife KD-655
5. Serial or Lot No.	from 59K to
6. Classification	Class IIb

7. Authorized representative in EU

Name	Olympus Europa SE & Co. KG
Address	Wendenstr. 14-18 20097 Hamburg, Germany

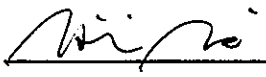
We hereby declare that the above mentioned product complies with the requirements of EC Directive 93/42/EEC(MDD)under the sole responsibility as a legal manufacturer. This Declaration of Conformity is valid in manufactured devices with the above Serial/Lot number.

This declaration is based on : MDD, Annex II.3

8. Notified Body Approval

Issued by	TÜV Rheinland LGA Products GmbH (0197)
Address	Tillystrasse 2, D-90431 Nürnberg, Germany

9. Applied Standards — Refer to the Essential Requirements Checklist for above mentioned product.

Place	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
Signature	
Name	Hiroki Moriyama
Title	General Manager Medical Quality Department Medical Quality & Regulatory Division
Date	2015/09/24

[N-OIS D28001 Appendix 3]

OLYMPUS

KeyMed (Medical and Industrial Equipment) Ltd
KeyMed House
Stock Road
Southend-on-Sea
SS2 5QH
United Kingdom
Telephone: +44 (0)1702 616333
e-mail:olympus@olympus.co.uk
Web: www.olympus.co.uk

MEDICAL DEVICE

EU DECLARATION OF CONFORMITY

Conformity route
Full Quality Assurance (Annex II)

Standard	Certificate Number
ISO 9001	FM 20993
ISO 13485	MD 83891
CE certificate	CE 00424

EU Medical Device Classification:

Class I (certified by manufacturer)	I	☐
	I(m)	☐
	I(s)	☐
Class II (certified by Notified Body)	IIa	☒
	IIb	☐
Notified Body Ref N°:	0086	

Declaration Number:	DC/1197-M/161	
Device:	**Part Number**	**Model**
	K10001143	OFP-2 (EU)
	K10001144	OFP-2 (UK)
	K10001145	OFP-2 (RoW)
Device Name:	Flushing Pump	

Accessory(s):	**Part Number**	**Model**
Water container (2L)	K10007071	MAJ-1603
Instrument Channel Adaptor	K10016091 K 10007072	MAJ-1606
Instrument Channel Water Tube	K10016136 K10001146	MAJ-1607
Auxiliary Channel Water Tube	K10016135 K10001147	MAJ-1608
Auxiliary Channel Water Tube Set	K10023086	MAJ-1651
Auxiliary Channel Adaptor	K10020736	MAJ-1652
Sterile Flushing Pump Tubing- via ET device	K10026641 K10025540	MAJ-1681
Sterile Flushing Pump Tubing with spike- via ET device	K10026029 K10026686	MAJ-1682

Quality Management System Conformity

This device has been designed, manufactured and tested under the control of a quality management system certified in accordance with Annex II of the Medical Device Directive (MDD) and meets other Directive requirements as indicated:

Applicable Directives	**Applicability**
Medical Device Directive 93/42/EEC as amended by 2007/47/EC (MDD)	☒
Restriction of Hazardous Substances Directive 2011/65/EU (RoHS2)	☒

ER Checklist Reference	**Issue**	**Date**
030	09	31 March 2016

Identification of conforming devices

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

Serial or batch number range **From** 20121040

To N/A

Date of entry of final serial or batch number and initials.
N/A

If "To" numbers are not entered, current production of the device/accessory is covered by this declaration.

Changes

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 up-issued and re-verification that the device meets the requirements of any applicable Directive carried out and recorded on a superseding declaration.

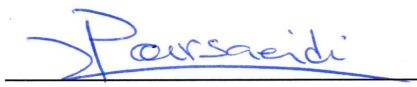
At the time of implementation of the design change into the product, the serial or batch numbers of the last items manufactured to the previous design will be entered in the "to" section above, thus recording the full range of items to which this declaration refers.

Product Conformity

I declare that on the basis of the information provided, the given serial or batch numbers of the device are in compliance with the Essential Requirements of Annex I of Directive 93/42/EEC and other applicable directives as indicated.

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.

Signed:



Print Name: R Poursaeidi

Position: Regulatory Affairs Manager ***Date: 18 May 2016***

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 192-8507 Japan

3. Model: NA-220H-8019、NA-220H-8022、NA-220H-8025、NA-230H-8022

4. Name of product: Single Use Aspiration Needle NA-220H/230H

5. Serial or Lot No.: from 15K to

6. Classification: Class IIa

7. Authorized representative in EU

■Name: Olympus Europa Holding GmbH

Address: Wendenstr. 14-18 20097 Hamburg, Germany

We hereby declare that the above mentioned product complies with the requirements of EC Directive 93/42/EEC(MDD)under the sole responsibility as a legal manufacturer. This Declaration of Conformity is valid in manufactured devices with the above Serial/Lot number.

This declaration is based on : MDD, Annex II.3

8. Notified Body Approval

Issued by: TÜV Rheinland LGA Products GmbH (0197)

Address: Tillystrasse 2, D-90431 Nürnberg, Germany

9. Applied Standards: Refer to the Essential Requirements Checklist for above mentioned product.

Place: 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan

Signature: 

Name: Seiya Raiju

Title: General Manager, Regulatory Affairs & Quality Assurance Department

Date: 2011/06/09

[N-OIS D28001 Appendix 3]

DECLARATION OF CONFORMITY(MDD)

OLYMPUS

1. Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.

2. Address: 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507 Japan

3. Model: PBD-1030-0705,PBD-1030-0706,PBD-1030-0707,PBD-1030-0708,PBD-1030-0709, PBD-1030-0710,PBD-1030-0711,PBD-1030-0712,PBD-1030-0713,PBD-1030-0714,PBD-1030-0715,PBD-1030-0716,PBD-1030-0717, PBD-1030-0718,PBD-1030-0805,PBD-1030-0806,PBD-1030-0807,PBD-1030-0808, PBD-1030-0809,PBD-1030-0810,PBD-1030-0811,PBD-1030-0812,BD-1030-0813,PBD-1030-0814,PBD-1030-0815,PBD-1030-0816,PBD-1030-0817,PBD-1030-0818,PBD-1030-1005,PBD-1030-1006,PBD-1030-1007,PBD-1030-1008,PBD-1030-1009,PBD-1030-1010,PBD-1030-1011,PBD-1030-1012,PBD-1030-1013,PBD-1030-1014,PBD-1030-1015,PBD-1030-1016,PBD-1030-1017,PBD-1030-1018,PBD-1030-1205,PBD-1030-1206,PBD-1030-1207,PBD-1030-1208,PBD-1030-1209,PBD-1030-1210,PBD-1030-1211,PBD-1030-1212,PBD-1030-1213,PBD-1030-1214,PBD-1030-1215,PBD-1030-1216,PBD-1030-1217,PBD-1030-1218, PBD-1031-0705,PBD-1031-0707,PBD-1031-0709,PBD-1031-0711,PBD-1031-0712,PBD-1031-0713,PBD-1031-0715,PBD-1031-0718,PBD-1031-0805,PBD-1031-0807,PBD-1031-0809,PBD-1031-0811,PBD-1031-0812,PBD-1031-0813,PBD-1031-0815,PBD-1031-0818,PBD-1031-1005,PBD-1031-1007,PBD-1031-1009,PBD-1031-1011,PBD-1031-1012,PBD-1031-1013,PBD-1031-1015,PBD-1031-1018,PBD-1031-1205,PBD-1031-1207,PBD-1031-1209,PBD-1031-1211,PBD-1031-1212,PBD-1031-1213,PBD-1031-1215,PBD-1031-1218,PBD-1032-0705,PBD-1032-0706,PBD-1032-0707,PBD-1032-0708,PBD-1032-0709,PBD-1032-0710,PBD-1032-0711,PBD-1032-0712,PBD-1032-0713,PBD-1032-0714,PBD-1032-0715,PBD-1032-0716,PBD-1032-0717,PBD-1032-0718,PBD-1032-0805,PBD-1032-0806,PBD-1032-0807,PBD-1032-0808,PBD-1032-0809,PBD-1032-0810,PBD-1032-0811,PBD-1032-0812,PBD-1032-0813,PBD-1032-0814,PBD-1032-0815,PBD-1032-0816,PBD-1032-0817,PBD-1032-0818,PBD-1032-1005,PBD-1032-1006,PBD-1032-1007,PBD-1032-1008,PBD-1032-1009,PBD-1032-1010,PBD-1032-1011,PBD-1032-1012,PBD-1032-1013,PBD-1032-1014,PBD-1032-1015,PBD-1032-1016,PBD-1032-1017,PBD-1032-1018,PBD-1032-1205,PBD-1032-1206,PBD-1032-1207,PBD-1032-1208,PBD-1032-1209,PBD-1032-1210,PBD-1032-1211,PBD-1032-1212,PBD-1032-1213,PBD-1032-1214,PBD-1032-1215,PBD-1032-1216,PBD-1032-1217,PBD-1032-1218,PBD-1033-0703,PBD-1033-0704,PBD-1033-0705,PBD-1033-0706,PBD-1033-0707, PBD-1033-0708,PBD-1033-0709, PBD-1033-0710, PBD-1033-0712,PBD-1033-0715

4. Name of product: Single Use Biliary Drainage Stent V

5. Serial or Lot No.: from 35K to

6. Classification: Class IIb

7. Authorized representative in EU

   Name: Olympus Europa Holding GmbH

   Address: Wendenstr. 14-18 20097 Hamburg, Germany

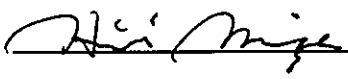
We hereby declare that the above mentioned product complies with the requirements of EC Directive 93/42/EEC(MDD)under the sole responsibility as a legal manufacturer. This Declaration of Conformity is valid in manufactured devices with the above Serial/Lot number.

This declaration is based on : MDD, Annex II.3

8. Notified Body Approval

Issued by	TÜV Rheinland LGA Products GmbH (0197)
Address	Tillystrasse 2, D-90431 Nürnberg, Germany

9. Applied Standards — Refer to the Essential Requirements Checklist for above mentioned product.

Place	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
Signature	
Name	Hiroki Moriyama
Title	Deputy General Manager Regulatory Affairs & Quality Assurance Department Quality & Environment Division
Date	2013/05/31

[N-OIS D28001 Appendix 3]