DECLARATION OF CONFORMITY(MDD)

OLYMPUS

1. Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.
2. Address	2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507 Japan
3. Model	BML-110A-1
4. Name of product	MECHANICAL LITHOTRIPTOR
5. Serial or Lot No.	from 84K to
6. Classification	Class I

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).

This declaration is based on : MDD, Annex VII

Place	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
Signature	
Name	Seiya Raiju
Title	General Manager, Regulatory Affairs & Quality Assurance Department
Date	2010/03/23(yyyy.mm.dd)

[N-OIS D28001 Appendix 2]
Revision 1 :2010/03/23 (yyyy.mm.dd)

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) BML-110A-1 MECHANICAL LITHOTRIPTOR

Model and Name of the related item	Class	Serial or Lot No.
MAJ-403(Coil Sheath)	I	from 84K to

Signature

Name Seiya Raiju

Title General Manager,
Regulatory Affairs & Quality Assurance Department

Date 2010/03/23(yyyy.mm.dd)

[N-OIS D28001 Appendix 6]
Revision 2 :2010/03/23 (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	FB-24E-1 FB-24K-1 FB-24Q-1 FB-24U-1 FB-36K-1 FB-37K-1 FB-37U-1
4. Name of product	BIOPSY FORCEPS
5. Serial or Lot No.	from K7901 to
6. Classification	Class I

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 VII

Place	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
Signature	
Name	Seiya Raiju
Title	General Manager, Regulatory Affairs & Quality Assurance Department
Date	2010/03/02(yyyy.mm.dd)

[N-OIS D28001 Appendix 2]
Revision 1 :2010/03/02 (yyyy.mm.dd)

DECLARATION OF CONFORMITY(MDD)

OLYMPUS

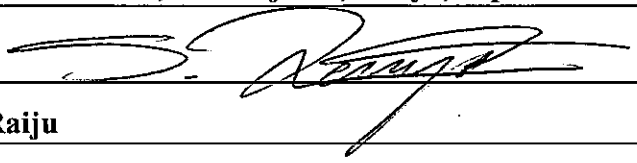
1. Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.
2. Address	2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507 Japan
3. Model	FG-22Q-1 FG-23Q-1
4. Name of product	GRASPING FORCEPS
5. Serial or Lot No.	FG-22Q-1 : from 79A to 8ZA,from 7XK to FG-23Q-1 : from 79A to 8ZA,from 7XK to
6. Classification	Class I

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).

This declaration is based on : MDD, Annex VII

Place	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
Signature	
Name	Seiya Raiju
Title	General Manager, Regulatory Affairs & Quality Assurance Department
Date	2010/05/12(yyyy.mm.dd)

[N-OIS D28001 Appendix 2]
Revision 1 :2010/05/12 (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	FG-44NR-1
4. Name of product	ROTATABLE GRASPING FORCEPS
5. Serial or Lot No.	from K7901 to
6. Classification	Class I

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 VII

Place	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
Signature	
Name	Seiya Raiju
Title	General Manager, Regulatory Affairs & Quality Assurance Department
Date	2010/03/03(yyyy.mm.dd)

[N-OIS D28001 Appendix 2]
Revision 1 :2010/03/03 (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	FG-45L-1 FG-45U-1 FG-46L-1 FG-46U-1
4. Name of product	GRASPING FORCEPS
5. Serial or Lot No.	from K7901 to
6. Classification	Class I

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 VII

Place	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
Signature	
Name	Seiya Raiju
Title	General Manager, Regulatory Affairs & Quality Assurance Department
Date	2010/03/03(yyyy.mm.dd)

[N-OIS D28001 Appendix 2]
Revision 1 :2010/03/03 (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	FG-301Q
4. Name of product	GRASPING FORCEPS
5. Serial or Lot No.	from 08K to
6. Classification	Class I

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).

This declaration is based on : MDD, Annex VII

Place	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
Signature	
Name	Seiya Raiju
Title	General Manager, Regulatory Affairs & Quality Assurance Department
Date	2010/03/23(yyyy.mm.dd)

[N-OIS D28001 Appendix 2]
Revision 1 :2010/03/23 (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-110LR, HX-110QR, HX-110UR
4. Name of product	Rotatable Clip Fixing Device
5. Serial or Lot No.	from 4ZK to
6. Classification	Class IIa

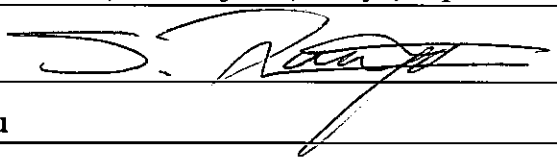
7. Authorized representatives in EU

■ 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).

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

[N-OIS D28001 Appendix 3]
Revision 2 :2010/05/20 (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	KD-301Q-0320/0330/0720/0725/0730/0735/1520/1530/3020/3030/3035 KD-321Q-0720/0730
4. Name of product	TRIPLE LUMEN SPHINCTEROTOME
5. Serial or Lot No.	from 97K to 8XK, from 8YK to
6. Classification	Class IIb

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).

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	2010/03/24(yyyy.mm.dd)

[N-OIS D28001 Appendix 3]
Revision 2 :2010/03/24 (yyyy.mm.dd)

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)
KD-301Q-0320/0330/0720/0725/0730/0735/1520/1530/3020/3030/3035 KD-321Q-0720/0730 TRIPLE LUMEN SPHINCTEROTOME

Model and Name of the related item	Class	Serial or Lot No.
MH-263(KD Handle)	I	from 7XA to 8XK, from 8YK to
MH-544(Sealing Assembly)	I	from 79R to 8XK,from 8YK to
MH-969(A Cord)	I	from 97K to 8XK, from 8YK to

Signature

Name Seiya Raiju

Title General Manager,
Regulatory Affairs & Quality Assurance Department

Date 2010/03/24(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: SD-5L-1 SD-5U-1 SD-6L-1 SD-6U-1 SD-7P-1 SD-8P-1 SD-9L-1 SD-9U-1 SD-11L-1 SD-11U-1 SD-12L-1 SD-12U-1 SD-13L-1 SD-13U-1 SD-16L-1 SD-16U-1 SD-17L-1 SD-17U-1
4. Name of product: ELECTROSURGICAL SNARE
5. Serial or Lot No.: from 79H to 8XK, from 8YK to
6. Classification: Class IIb
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: 2010/03/08(yyyy.mm.dd)

[N-OIS D28001 Appendix 3]
Revision 2 :2010/03/08 (yyyy.mm.dd)

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) SD-5L-1 SD-5U-1 SD-6L-1 SD-6U-1 SD-7P-1 SD-8P-1 SD-9L-1 SD-9U-1 SD-11L-1 SD-11U-1 SD-12L-1 SD-12U-1 SD-13L-1 SD-13U-1 SD-16L-1 SD-16U-1 SD-17L-1 SD-17U-1 ELECTROSURGICAL SNARE

Model and Name of the related item	Class	Serial or Lot No.
MA-430(Wire Leader)	I	from 98/03/27 to
MA-431(Wire Leader)	I	from 98/03/27 to
MAJ-10(SNARE TUBE)	IIa	from 98/03/27 to
MAJ-11(SNARE WIRE)	IIb	from 98/10/01 to 8XK, from 8YK to
MAJ-12(SNARE WIRE)	IIb	from 98/10/01 to 8XK, from 8YK to
MAJ-13(SNARE TUBE)	IIa	from 98/03/27 to
MAJ-14(SNARE WIRE)	IIb	from 98/10/01 to 8XK, from 8YK to
MAJ-15(SNARE TUBE)	IIa	from 98/03/27 to
MAJ-16(SNARE WIRE)	IIb	from 98/10/01 to 8XK, from 8YK to
MAJ-17(SNARE WIRE)	IIb	from 98/10/01 to 8XK, from 8YK to
MAJ-18(SNARE WIRE)	IIb	from 98/10/01 to 8XK, from 8YK to
MAJ-19(SNARE WIRE)	IIb	from 98/10/01 to 8XK, from 8YK to
MAJ-20(SNARE WIRE)	IIb	from 98/10/01 to 8XK, from 8YK to
MAJ-21(SNARE WIRE)	IIb	from 98/10/01 to 8XK, from 8YK to
MH-969(A Cord)	I	from 97K to 8XK, from 8YK to

Signature

Name Seiya Raiju

Title General Manager,
Regulatory Affairs & Quality Assurance Department

Date 2010/03/08(yyyy.mm.dd)

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) SD-5L-1 SD-5U-1 SD-6L-1 SD-6U-1 SD-7P-1 SD-8P-1 SD-9L-1 SD-9U-1 SD-11L-1 SD-11U-1 SD-12L-1 SD-12U-1 SD-13L-1 SD-13U-1 SD-16L-1 SD-16U-1 SD-17L-1 SD-17U-1 ELECTROSURGICAL SNARE

Model and Name of the related item	Class	Serial or Lot No.
MAJ-216(SNARE WIRE)	IIb	from 98/10/01 to 8XK, from 8YK to
MAJ-217(SNARE TUBE)	IIa	from 98/03/27 to
MAJ-218(SNARE WIRE)	IIb	from 98/10/01 to 8XK, from 8YK to
MAJ-219(SNARE TUBE)	IIa	from 98/03/27 to
MAJ-22(SNARE WIRE)	IIb	from 98/10/01 to 8XK, from 8YK to
MAJ-220(SNARE WIRE)	IIb	from 98/10/01 to 8XK, from 8YK to
MAJ-221(SNARE WIRE)	IIb	from 98/10/01 to 8XK, from 8YK to
MAJ-23(SNARE WIRE)	IIb	from 98/10/01 to 8XK, from 8YK to
MAJ-24(SNARE WIRE)	IIb	from 98/10/01 to 8XK, from 8YK to
MAJ-25(SNARE WIRE)	IIb	from 98/10/01 to 8XK, from 8YK to
MAJ-26(SNARE WIRE)	IIb	from 98/10/01 to 8XK, from 8YK to
MH-264(SD Handle)	I	from 79H to 8XK, from 8YK to

Signature

Name Seiya Raiju

Title General Manager,
Regulatory Affairs & Quality Assurance Department

Date 2010/03/08(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	NM-4L-1,NM-5L-1,NM-6L-1,NM-7L-1,NM-8L-1,NM-9L-1,NM-4U-1
4. Name of product	INJECTOR
5. Serial or Lot No.	from 79R to 95R, NM-4L/8L/4U-1:from 6YK to, NM-5L/6L-1:from 68K to, NM-7L/9L-1:from 6XK to
6. Classification	Class IIa

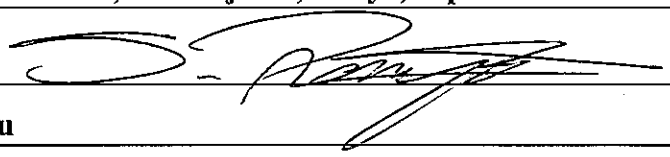
7. Authorized representatives in EU

■ 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).

This declaration is based on : MDD, Annex II

8. Certification of a quality system : Issued by TÜV Rheinland LGA Products GmbH (0197)

Place	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
Signature	
Name	Seiya Raiju
Title	General Manager, Regulatory Affairs & Quality Assurance Department
Date	2010/03/31(yyyy.mm.dd)

[N-OIS D28001 Appendix 3]
Revision 1 :2010/03/31 (yyyy.mm.dd)

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)
NM-4L-1,NM-5L-1,NM-6L-1,NM-7L-1,NM-8L-1,NM-9L-1,NM-4U-1 INJECTOR

Model and Name of the related item	Class	Serial or Lot No.
MAJ-67(NA-SHEATH)	IIa	from 8XR to 95R,from 6YK to
MAJ-68(NM-NEEDLE)	IIa	from 79R to 95R,from 6YK to
MAJ-69(NA-SHEATH)	IIa	from 8XR to 95R,from 6YK to
MAJ-70(NA-NEEDLE)	IIa	from 79R to 95R,from 6YK to
MAJ-71(NA-NEEDLE)	IIa	from 79R to 95R,from 68K to
MAJ-72(NA-NEEDLE)	IIa	from 79R to 95R,from 68K to
MAJ-73(NA-NEEDLE)	IIa	from 79R to 95R,from 6XK to
MAJ-74(NA-SHEATH)	IIa	from 8XR to 95R,from 6XK to
MAJ-75(NA-NEEDLE)	IIa	from 79R to 95R,from 6YK to
MAJ-76(NA-NEEDLE)	IIa	from 79R to 95R,from 6XK to

Signature

Name Seiya Raiju

Title General Manager,
Regulatory Affairs & Quality Assurance Department

Date 2010/03/31(yyyy.mm.dd)

[N-OIS D28001 Appendix 6]
Revision 3 :2010/03/31 (yyyy.mm.dd)

OLYMPUS

DECLARATION OF CONFORMITY(MDD)

1. Manufacturer: Olympus Optical Co., Ltd.
2. Address: 43-2, Hatagaya 2 Chome, Shibuya-ku, Tokyo, Japan
3. Model: BML-1Q-1 BML-2Q-1 BML-3Q-1 BML-4Q-1 MAJ-237 MAJ-238 MAJ-239 MAJ-240 MAJ-241 MAJ-242 MAJ-243 MAJ-244 MAJ-245 MAJ-246 MAJ-247
4. Name of product: MECHANICAL LITHOTRIPTOR
5. Serial or Lot No.: from 23K to
6. Classification: Class I
7. Authorized representatives in EU

■ Name: Olympus Opt.Co.(Europe) 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: Kazuma Kawashima

Management Representative, Medical Systems Group

2002/11/27(yyyy.mm.dd)

[N-OIS D28001 Appendix 2]
Revision 1 :2002/11/27 (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	PR-304Q/309Q/310Q/313Q/326Q
4. Name of product	CANNULA
5. Serial or Lot No.	from 31K to
6. Classification	Class I

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).

This declaration is based on : MDD, Annex VII

Place	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
Signature	
Name	Seiya Raiju
Title	General Manager, Regulatory Affairs & Quality Assurance Department
Date	2010/03/23(yyyy.mm.dd)

[N-OIS D28001 Appendix 2]
Revision 1 :2010/03/23 (yyyy.mm.dd)