Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat al dispozitivelor medicale

nr. 1 din **21.09.2023**

Solicitantul **FCPC „DataControl" S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemitanu 17/6** tel./fax: 022 27 37 12, e-mail: contact@datacontrol.md, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Olympus:

1. WA2T400A
2. A3551
3. A3552
4. A3554
5. A3550
6. WA35055A
7. WA33037A
8. WA33025A
9. A0555

Se anexează următoarele acte:
1. Declarație de Conformitate
2. Certificatul de conformitate CE
3. Scrisoare de autorizare

Data **21.09.2023** Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	

Digitally signed by Grabazei Alexandru
Date: 2023.09.21 08:46:59 EEST
Reason: MoldSign Signature
Location: Moldova

Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **FCPC „DataControl" S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemitanu 17/6** tel./fax: 022 27 37 12, e-mail: contact@datacontrol.md,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Olympus:

1. WA2T400A
2. A3551
3. A3552
4. A3554
5. A3550
6. WA35055A
7. WA33037A
8. WA33025A
9. A0555

Sunt autentice și corespund realității.

Grabazei Alexandru, director general *Semnătura* _____

Data **16.09.2023**

OLYMPUS

Date: 30.08.2023

Authorization

We, the undersigned OLYMPUS EUROPA SE & CO. KG, Wendenstraße 20, 20097 Hamburg, Germany, herby we appoint F.C.P.C. "DataControl" S.R.L., 17/6, N.Testimiteanu street, MD-2025, Chişinau, Republic of Moldova, to be authorized distributor/representative for registration, renewal, amendments of registration, at the responsible authorities of the Republic of Moldova.

Senior Distributor Channel and Emerging Markets Manager
Medical Systems Division
OLYMPUS EUROPA SE & CO. KG

Dmitry Mitrofanov

OLYMPUS EUROPA SE & CO. KG
Wendenstraße 20, 20097 Hamburg, Postfach 10 49 08, 20034 Hamburg, Telefon +49 40 23773-0, Fax +49 40 233765
Sitz der Kommanditgesellschaft: Hamburg, Handelsregister: Amtsgericht Hamburg HRA 116518
Komplementärin: Olympus Europa Management SE
Geschäftsführende Direktoren: Carl Constantin Zangemeister (Executive Managing Director), Miquel-Àngel García, Marion Bönsch, Dr. Christian Meyer, Nacho Abia
Vorsitzender des Verwaltungsrates: Carl Constantin Zangemeister
Sitz der Komplementärin: Hamburg · Handelsregister: Amtsgericht Hamburg HRB 126986

Art.-Nr. 9958688

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60149405 0001

Report No.: 12018179 053

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo
192-8507 Japan

Products: Design and Development, Manufacture of Medical Endoscopy Systems, Diagnostic, Operation and Treatment Products

(see attachments for products included)

Replaces Approval, Registration No.: HD 60144066 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-05-12

Date: 2020-05-12

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Notified Body

M.Aihara

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60149405 0001
Report No.: 12018179 053

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo
192-8507 Japan

Products included:

Medical Endoscopy Systems:
-Endoscopes
-Endotherapy Devices
-Imaging Processors
-Pumps for Endoscopy
-Light Sources
-Position Detecting Units
-Electrothermal Cautery Units
-Integrated Endosurgery Systems
-Endoscopic Regulation/Control Units
Electrosurgical Equipment
Probes and Transducers for Ultrasonic Lithotriptors
Laparoscopic Insufflators
Ultrasound Surgical Equipment
Ultrasonic Surgical System generator
Ultrasonic Surgical System transducer
Hard-tissue ultrasonic surgical system holder/tip
Disinfecting Units
Capsule Endoscopes and Systems
Ultrasound Diagnostic Imaging Systems

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-05-12

M.Aihara

M.Sc. M. Aihara

Traducere din limba engleza

TÜVRheinland®

CERTIFICAT CE

Directiva CE 93/42/CEE Anexa II, excluzând Secţiunea 4
Sistem complet de asigurare a calităţii
Echipamente medicale

Nr. Înregistrare: HD 60149405 0001
Nr. Raport: 12018179 053

Producător: **Olympus Medical Systems Corp.**
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse: Proiectare şi dezvoltare, producţie de sisteme de endoscopie medicală, produse de diagnostic, operaţie şi tratament.
(a se vedea atasamentele pentru produsele incluse)
Înlocuieşte Aprobarea cu nr. de înregistrare: HD 60144066 0001

Data expirarii: 26.05.2024

Organismul Notificat declară prin prezenta că au fost îndeplinite cerinţele Anexei II, excluzând secţiunea 4 a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menţionat a stabilit şi aplică un sistem de asigurare a calităţii, care este supus unei supravegheri periodice, definită în Anexa II, secţiunea 5 a directivei menţionate anterior. Pentru comercializarea echipamentelor din clasa III acoperite de acest certificat, este necesar un certificat CE de examinare proiectare în conformitate du Anexa II, secţiunea 4.

Organism notificat
Ştampilă:
TUV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)

Data intrării în vigoare: 12-05-2020

Data: 12.05.2020

TŰV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nűrnberg
TŰV Rheinland LGA Products GmbH este un Organism Notificat în conformitate cu Directiva 93/42/CEE cu privire la echipamentele medicale, cu numărul de identificare 0197

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ • FRANCEZĂ
AUT. NR. 22069
TEL. 0745471462

TÜVRheinland®

Doc. 1/1 Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Atasament la
Certificat

Nr. Înregistrare: HD 60149405 0001
Nr. Raport: 12018179 053

Producător: **Olympus Medical Systems Corp.**
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse incluse:

- Sisteme medicale de endoscopie:
  - -Endoscoape
  - -Echipamente endoterapie
  - -Procesoare de imagine
  - -Pompe pentru endoscopie
  - -Surse de lumină
  - -Unităţi de detectare poziţie
  - -Unităţi de cauterizare electrotermică
  - -Sisteme endochirurgicale integrate
  - - Unitati de control/reglare endoscopice
- Echipamente electrochirurgicale
- Sonde şi traductoare pentru litotriptoare cu ultrasunete
- Insuflatoare laparoscopice
- Echipamente chirurgicale cu ultrasunete
- Generator sistem chirurgical cu ultrasunete
- Traductor sistem chirurgical cu ultrasunete
- Suport/varf sistem chirurgical cu ultrasunete pentru tesut tare
- Unitati de sterilizare
- Sisteme şi endoscoape capsulă
- Sisteme de imagistica pentru diagnostic cu ultrasunete

Organism notificat
Ştampilă:
TUV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)

Data: 12.05.2020

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL. 0745471462

OLYMPUS

EU - KONFORMITÄTSERKLÄRUNG
EC - DECLARATION OF CONFORMITY

Unternehmen: *Company*	Olympus Winter & Ibe GmbH Kuehnstr. 61 22045 Hamburg, Germany P.O.Box 70 17 09 22017 Hamburg, Germany Telefon: +49 (40) 6 69 66-0 Telefax: +49 (40) 6 69 66-2109
Hiermit erklären wir, dass das Produkt *We herewith declare that the product*	
Produktname: *Product name:*	Siehe angehängte Produktliste / *see attached List of Related Items*
Katalog Nr./ Modellname: *Catalog No./ Modelname:*	Siehe angehängte Produktliste / *see attached List of Related Items*
Beginnend mit Seriennummer / Lot: *Beginning with Serial-No / Lot:*	Siehe angehängte Produktliste / *see attached List of Related Items*
Produktfamilie: *Product Family:*	PF013 - KNIVES
Produktklassifizierung: *Product classification:*	IIa
die Anforderungen der Medizinprodukte Richtlinie 93/42/EEC erfüllt ***complies with the requirements of the Medical Device Directive 93/42/EEC.***	
Diese Erklärung bezieht sich auf: *This declaration is based on:*	Anhang II Annex II
Notifizierte Stellen für Produkte der Klasse Is, Im, IIa, IIb *Notified Body for products of class Is, Im, IIa, IIb:* TÜV Rheinland LGA Products GmbH – Tillystr. 2 – 90431 Nürnberg, Registration- Nr/No: 0197	

	Funktion *Function*	**Name** *Name*	**Datum** *Date*	**Unterschrift** *Signature*
Genehmigt *Approved by*	GM Q&R	Martin Peters	2015 -10- 09	

OLYMPUS

PRODUKTLISTE
LIST OF RELATED ITEMS

Diese EG-Konformitätserklärung gilt für nachfolgende Produkte
This Declaration of Conformity covers following items:

PF013 – KNIVES

Produkt Name/ *Product Name*	REF:	Beginnend mit: *Beginning with:* Serial-No / Lot
Messer, Wellenschliff, gerade / *Knife, corrugated, straight*	WA35057A	157W
Messer, lanzettförmig, gerade / *Knife, lancet type, straight*	WA35055A	157W
Messer, halbrund, mit 5 Ch. Kanal, für A3523 / *Knife, semi-circular, with 5 Fr. channel, for A3523*	O3526	95W
Messer, lanzettförmig, für A3523 / *Knife, lancet type, for A3523*	O3525	96W
Messer, halbrund, für A2523 / *Knife, semi-circular, for A2523*	O3524	96W
Messer, gerade, für A37014A, steril, zur Einmalverwendung / *Knife, straight, for A37014A, sterile, for single use*	A37010A	16W 01
Messer, Haken, für A37014A, steril, zur Einmalverwendung / *Knife, hook, for A37014A, sterile, for single use*	A37009A	99277
Messer, rund, für A37014A, steril, zur Einmalverwendung / *Knife, round, for A37014A, sterile, for single use*	A37008A	991592
Messer, Wellenschliff, für A3573 / *Knife, corrugated, for A3573*	A3577	92W 01
Messer, halbrund, 4 Ch. Kanal, für A3573/ *Knife, semi-circular, 4 Fr. channel, for A3573*	A3576	92W 01
Messer, lanzettförmig, für A3573/ *Knife, lancet type, for A3573*	A3575	96W 01
Messer, halbrund, für A3573/ *Knife, semi-circular, for A3573*	A3574	94W 01
Messer, halbrund, flexible Spitze, für A3550/ *Knife, semi-circular, flexible tip, for A3550*	A3559	154W 01
Messer, halbrund, für A3550/ *Knife, semi-circular, for A3550*	A3558	158W
Messer, Wellenschliff, für A3550/ *Knife, corrugated, for A3550*	A3557	159W
Messer, halbrund, 4 Ch. Kanal, für A3550/ *Knife, semi-circular, 4 Fr. channel, for A3550*	A3556	158W
Messer, lanzettförmig, für A3550/ *Knife, lancet type, for A3550*	A3555	157W
Ersatz-Messer, für A3328/ *Spare knife, for A3328*	A3329	9YW
Messer, geführt/ *Knife, guided*	A3328	152W
Messer, flexible Spitze, lang, 2 x 355 mm/ *Knife, flexible tip, long, 2 x 355 mm*	A2588	7YW
Messer, 24-28 Ch., 12° und 30°, Steril, Einmalverwendung,12 Stk./ *Knife, 24-28 Fr., 12° and 30°, sterile, single use, 12 pcs.*	A22265C	1YW
Kürette, 24-28 Ch., 12° und 30°/ *Curette, 24-28 Fr., 12° and 30°*	A22261A	1ZW

OLYMPUS

PF001 TELESCOPES, AUTOCLAVABLE (WITHOUT CHANNEL)EU - KONFORMITÄTSERKLÄRUNG
EC - DECLARATION OF CONFORMITY

Unternehmen: *Company*	Olympus Winter & Ibe GmbH Kuehnstr. 61 22045 Hamburg, Germany P.O.Box 70 17 09 22017 Hamburg, Germany Telefon: +49 (40) 6 69 66-0 Telefax: +49 (40) 6 69 66-2109
Hiermit erklären wir, dass das Produkt *We herewith declare that the product*	
Produktname: *Product name:*	see List of Related Items
Katalog Nr./ Modellname: *Catalog No./ Modelname:*	see List of Related Items
Beginnend mit Seriennummer / Lot: *Beginning with Serial-No / Lot:*	see List of Related Items
Produktfamilie: *Product Family:*	PF001Telescopes, autoclavable (without channel)
Produktklassifizierung: *Product classification:*	see List of Related Items
die Anforderungen der Medizinprodukte Richtlinie 93/42/EEC erfüllt ***complies with the requirements of the Medical Device Directive 93/42/EEC.***	
Diese Erklärung bezieht sich auf: *This declaration is based on:*	Annex II for products of class IIa
Notifizierte Stellen für Produkte der Klasse Is, Im, IIa, IIb *Notified Body for products of class Is, Im, IIa, IIb:* TÜV Rheinland LGA Products GmbH – Tillystr. 2 – 90431 Nürnberg, Registration- Nr/No: 0197	

	Funktion *Function*	**Name** *Name*	**Datum** *Date*	**Unterschrift** *Signature*
Genehmigt *Approved by*	GM Q&R	Dr. Martin Peters	19.08.2015	

OLYMPUS

LIST OF RELATED ITEMS

Following products belong to the Product-Family:

PF001-TELESCOPES, AUTOCLAVABLE

(WITHOUT CHANNEL)

Product Name:	Catalogue No/ Model Name:	MDD Class	Beginning with Serial-No / Lot
Telescope, 0°, 4 mm, autoclavable	A22000A	IIa	107608
Telescope, 12°, 4 mm, autoclavable	A22001A	IIa	107615
Telescope, 30°, 4 mm, autoclavable	A22002A	IIa	107625
Telescope, 70°, 4 mm, autoclavable	A22003A	IIa	107640
Telescope, 110°, 4 mm, autoclavable	A22004A	IIa	107817
Telescope, 30°, wideangle, 4 mm, autoclavable	A22005A	IIa	107635
Telescope, 1.9 mm, 0°, 210 mm, autoclavable	A3764A	IIa	000997
Telescope, 1.9 mm, 30°, 210 mm, autoclavable	A3765A	IIa	003014
Telescope, 3 mm, 0°, autoclavable	A4672A	IIa	807561
Telescope, 3 mm, 12°, autoclavable	A4673A	IIa	704205
Telescope, 3 mm, 30°, wideangle, autoclavable	A4674A	IIa	604887
Telescope, 1.9 mm, 0°, 280 mm, autoclavable	A4676A	IIa	009671
Telescope, 1.9 mm, 30°, 280 mm, autoclavable	A4677A	IIa	014810
Telescope, 5.4 mm, 30°, short, autoclavable	A4881A	IIa	406395
Telescope "TrueView II", 4 mm, 0°, autoclavable	A70940A	IIa	008408
Telescope "TrueView II", 4 mm, 30°, autoclavable	A70941A	IIa	008410
Telescope "TrueView II", 4 mm, 70°, autoclavable	A70942A	IIa	008414
Telescope "TrueView II", 2.7 mm, 0°, autoclavable	A70960A	IIa	100027
Telescope "TrueView II", 2.7 mm, 30°, autoclavable	A70961A	IIa	100033
Telescope "TrueView II", 2.7 mm, 70°, autoclavable	A70962A	IIa	101246
Telescope "TrueView II", 2.7 mm, 30°, short, auto-clavable	A70963A	IIa	100021
Telescope, 1.9 mm, 0°, 65 mm, autoclavable	A7504A	IIa	004197
Telescope, 1.9 mm, 30°, 65 mm, autoclavable	A7505A	IIa	004196
Telescope, 1.9 mm, 0°, 115 mm, autoclavable	A7506A	IIa	004189
Telescope, 1.9 mm, 30°, 115 mm, autoclavable	A7507A	IIa	004186
Telescope, 4 mm, 0°, angled, autoclavable	A81000A	IIa	000901

2015-09-28

OLYMPUS

Product Name:	Catalogue No/ Model Name:	MDD Class	Beginning with Serial-No / Lot
Telescope, 4 mm, 30°, angled, autoclavable	A81001A	IIa	000905
Telescope, 4 mm, 70°, angled, autoclavable	A81002A	IIa	000909
Telescope, 2.7 mm, 0°, angled, autoclavable	A81010A	IIa	000912
Telescope, 2.7 mm, 30°, angled, autoclavable	A81011A	IIa	000916
Telescope, 2.7 mm, 70°, angled, autoclavable	A81012A	IIa	000920
Telescope, 4 mm, 30°, angled, autoclavable	A81031A	IIa	311484
Telescope, 4 mm, 70°, angled, autoclavable	A81032A	IIa	311538
Telescope, 2.7 mm, 30°, angled, autoclavable	A81041A	IIa	300003
Telescope, 2.7 mm, 70°, angled, autoclavable	A81042A	IIa	311533
Telescope, 4 mm, 12°, autoclavable	WA20016A	IIa	515009
Telescope, 4 mm, 30°, autoclavable	WA20017A	IIa	535074
Telescope, 4 mm, 70°, autoclavable	WA20018A	IIa	515004
Telescope, 4 mm, 12°, long, autoclavable	WA20021A	IIa	405387
Telescope, 4 mm, 70°, long, autoclavable	WA20023A	IIa	405389
Telescope "OES ELITE", 4 mm, 0°, HD, autoclavable	WA2T400A	IIa	675379
Telescope "OES ELITE", 4 mm, 12°, HD, autoclavable	WA2T412A	IIa	674582
Telescope "OES ELITE", 4 mm, 30°, HD, autoclavable	WA2T430A	IIa	674642
Telescope "OES ELITE", 4 mm, 30°, wide-angle, HD, autoclavable	WA2T43WA	IIa	674632
Telescope "OES ELITE", 4 mm, 70°, HD, autoclavable	WA2T470A	IIa	675735
Telescope "OES ELITE", 4 mm, 12 °, PDD, HD, autoclavable	WA2T412P	IIa	675398
Telescope, 5.4 mm, 0°, autoclavable	WA50372B	IIa	203872
Telescope, 5.4 mm, 30°, autoclavable	WA50373B	IIa	204335
Telescope, 5.4 mm, 45°, autoclavable	WA50374B	IIa	203812
Telescope, 10 mm, 30°, 460 mm, quick lock, autoclavable	WA52005A	IIa	401293
Telescope, 10 mm, 45°, 460 mm, quick lock, autoclavable	WA52006A	IIa	401298
Telescope, 10 mm, 0°, HD, quick lock, autoclavable	WA53000A	IIa	406319
Telescope, 10 mm, 30°, HD, quick lock, autoclavable	WA53005A	IIa	406410
Telescope, 10 mm, 45°, HD, quick lock, autoclavable	WA53010A	IIa	406418
Telescope, 10 mm, 70°, autoclavable	WA96100A	IIa	544026
Telescope, 10 mm, 90°, autoclavable	WA96105A	IIa	544031
Telescope, 4 mm, 0°, connector for light guide on bottom, autoclavable	WA96200A	IIa	548585

OLYMPUS

Product Name:	Catalogue No/ Model Name:	MDD Class	Beginning with Serial-No / Lot
Telescope, 4 mm, 30°, connector for light guide on bottom, autoclavable	WA96201A	IIa	548586
Telescope, 4 mm, 30°, connector for light guide on top, autoclavable	WA96202A	IIa	548587
Telescope, 4 mm, 45°, connector for light guide on bottom, autoclavable	WA96203A	IIa	548588
Telescope, 4 mm, 45°, connector for light guide on top, autoclavable	WA96204A	IIa	548589
Telescope, 4 mm, 70°, connector for light guide on bottom, autoclavable	WA96205A	IIa	548590
Telescope, 4 mm, 70°, connector for light guide on top, autoclavable	WA96206A	IIa	545591
Telescope "OES ELITE", 4 mm, 30 °	WA2T430P	IIa	677201
Telescope "OES ELITE", 4 mm, 70 °	WA2T470P	IIa	647155

Change Log

Rev.	Date	Prepared by	Description of Changes	CR-No.
00	22.08.2013	B.Lange	Newly issued to cover the product family in one document	---
01	25.07.2014	B.Lange	New item WA2T412A added	E-871
02	04.08.2014	B.Lange	New item added: WA2T430A	E-871
03	20.08.2014	B.Lange	New item added: WA2T43WA	E-871
04	10.09.2014	B.Lange	New items added: WA2T400A, WA2T470A	E-871
05	19.09.2014	B.Lange	New item added: WA2T412P	E-871
06	2015-05-22	B.Lange	Annex VII removed from list of applicable Annexes	---
07	2015-08-13	B.Kappertz	New item added: WA2T430P, WA2T470P	E-0871

2015-09-28

OLYMPUS

EU - KONFORMITÄTSERKLÄRUNG
EC - DECLARATION OF CONFORMITY

Unternehmen: *Company*	Olympus Winter & Ibe GmbH Kuehnstr. 61 22045 Hamburg, Germany P.O.Box 70 17 09 22017 Hamburg, Germany Telefon: +49 (40) 6 69 66-0 Telefax: +49 (40) 6 69 66-2109
Hiermit erklären wir, dass das Produkt *We herewith declare that the product*	
Produktname: *Product name:*	Schaft, 22 Ch., für Urethrotom Sheath, 22 Fr., for urethrotome
Katalog Nr./ Modellname: *Catalog No./ Modelname:*	A3551
Beginnend mit Seriennummer / Lot: *Beginning with Serial-No / Lot:*	15XW
Produktfamilie: *Product Family:*	-/-
Produktklassifizierung: *Product classification:*	IIa
die Anforderungen der Medizinprodukte Richtlinie 93/42/EEC erfüllt ***complies with the requirements of the Medical Device Directive 93/42/EEC.***	
Diese Erklärung bezieht sich auf: *This declaration is based on:*	Anhang II Annex II
Notifizierte Stellen für Produkte der Klasse Is, Im, IIa, IIb *Notified Body for products of class Is, Im, IIa, IIb:* TÜV Rheinland LGA Products GmbH – Tillystr. 2 – 90431 Nürnberg, Registration- Nr/No: 0197	

	Funktion *Function*	**Name** *Name*	**Datum** *Date*	**Unterschrift** *Signature*
Genehmigt *Approved by*	GM Q/R	Dr. Martin Peters	2015 -10- 22	

OLYMPUS

EC – DECLARATION OF CONFORMITY
EG - KONFORMITÄTSERKLÄRUNG

Manufacturer: *Hersteller:*	**Olympus Surgical Technologies Europe** **Olympus Winter & Ibe GmbH** Kuehnstr. 61 / 22045 Hamburg / Germany P.O. Box 70 17 09 / 22017 Hamburg / Germany Phone: +49 (40) 6 69 66-0 / Fax: +49 (40) 6 69 66-2109
Product designation: *Produktbezeichnung:*	**16650, Syringes, Aspirating** **16650, Spritze, Absaugung**
Article (REF) No. / Article name: *Artikel (REF) Nr. / Artikelname:*	**See attachment 1** *siehe Anhang 1*
Beginning with Serial No. / Lot: *Beginnend mit Serien Nr. / Lot:*	**See attachment 1** *siehe Anhang 1*
Product classification: *Produktklassifizierung:*	**See attachment 1** *siehe Anhang 1*

CE

This declaration was made in solo responsibility of the manufacturer.
Diese Erklärung wurde in alleiniger Verantwortung des Herstellers erstellt.
The stated product complies with the requirements of following European Directives:
Das angegebene Produkt erfüllt die Anforderungen der folgenden Europäischen Richtlinien:

The declaration is based on: *Die Erklärung bezieht sich auf:*	**93/42/EEC / Annex II** *93/42/EWG / Annex II*	**Medical Device Directive** *Medizinproduktrichtlinie*

The conformity with the directive(s) is given by the following standards:
Die Konformität mit der Richtlinie / den Richtlinien ist gegeben durch die Einhaltung der folgenden Normen:

Harmonised European Standards: *Harmonisierte Europäische Normen:*	-/-
National Standards: *Nationale Normen und Vorschriften:*	-/-
Notified body for products of class Is, Im, IIa, IIb: ***Benannte Stelle*** *für Produkte der Klasse: Is, Im, IIa, IIb:*	**TÜV Rheinland LGA Products GmbH** Tillystraße 2, 90431 Nürnberg, Germany Registration-No./Nr. 0197
Place, Date: *Ort, Datum:*	Hamburg, 2017-11-03
Signature: *Unterschrift:*	Department Manager Regulatory Affairs Jan-Michael Krüger

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ATTACHMENT 1

Anhang 1

The EC-Declaration of Conformity is valid for the following articles:

Die EG-Konformitätserklärung ist gültig für die folgenden Artikel:

Product designation *Produktbezeichnung*	**Article (REF) No. / Article name** *Artikel (REF) Nr. / Artikelname*	**Beginning with Serial No. / Lot** *Beginnend mit Serien Nr. / Lot*	**Product classification*** *Produkt-klassifizierung**
16650, Syringes, Aspirating **16650, Spritze, Absaugung**	**A0555 / Syringe, 150 ml, with flexible clamping cone** *A0555 / Spritze, 150 ml, mit flexiblem Spannkonus*	**W1710001**	**Class I** Annex IX, Rule 2 *Klasse I* *Anhang IX, Regel 2*
16650, Syringes, Aspirating **16650, Spritze, Absaugung**	**A0556 / Syringe, 150 ml, with clamping cone** *A0556 / Spritze, 150 ml, mit Spannkonus*	**W1710001**	**Class I** Annex IX, Rule 2 *Klasse I* *Anhang IX, Regel 2*
16650, Syringes, Aspirating **16650, Spritze, Absaugung**	**A0558 / Spare cylinder, for A0555** *A0558 / Ersatz-Zylinder, für A0555*	**W1710001**	**Class I** Annex IX, Rule 2 *Klasse I* *Anhang IX, Regel 2*
16650, Syringes, Aspirating **16650, Spritze, Absaugung**	**A0559 / Spare cylinder, for A0556** *A0559 / Ersatz-Zylinder, für A0556*	**W1710001**	**Class I** Annex IX, Rule 2 *Klasse I* *Anhang IX, Regel 2*

*: based on 93/42/EEC Annex IX / basierend auf 93/42/EWG Anhang 9