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. 2 din 11.06.2023

Solicitantul **FCPC „DataControl" S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemițanu, 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 MEDICAL SYSTEM CORP.

Product: Medical Endoscopy System, Diagnostic, Operation and Treatment
Model:

1. **OTV-S200**
2. **CH-S200-XZ-EA**
3. **UHI-4**

Se anexează următoarele acte:

1. Certificat CE
2. Actul prin care producătorul își desemnează reprezentantul
3. Declarație pe propria răspundere.

Data **03.07.2023** 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)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Grabazei Alexandru
Date: 2023.07.03 10:13:38 EEST
Reason: MoldSign Signature
Location: Moldova

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitantul **F.C.P.C. ”DataControl” S.R.L.**, cu sediul în **mun. Chișinău, str. N. Testemițanu 17/6**, tel./fax: **022 27 37 12**, e-mail: contact@datacontrol.md,

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

Product: Medical Endoscopy System, Diagnostic, Operation and Treatment
Model:

1. **OTV-S200**
2. **CH-S200-XZ-EA**
3. **UHI-4**

Sunt autentice și corespund realității

Alexandru Grabazei, director Semnătura _____
Data: **03.07.2023**

OLYMPUS

Your Vision, Our Future

Hamburg, 19 Oct 2017

Authorization

We, the undersigned, Olympus Europa SE & Co. KG, Amsinckstrasse 63, 20097 Hamburg/Germany, hereby appoint F.C.P.C. "DataControl" S.R.L., 20, Melestiu street, MD-2001, Chișinau, Republic of Moldova, to be our official representative for registration, renewal, variation of registration, etc. at the responsible authorities of the Republic of Moldova.

OLYMPUS EUROPA SE & CO. KG
AMSINCKSTR. 63
20097 HAMBURG
GERMANY

Dr. Harald Dremel
Director Medical Endoscopy Group

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 TÜVRheinland Zertifizierungsstelle

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.Sc. M. Aihara

TÜVRheinland®

EC Certificate

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

Registration No.: HD 60151129 0001

Report No.: 21232416 020

Manufacturer:
Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Deutschland

Products: medical endoscopy, surgical, diagnostic, and treatment systems

(see attachment for products and sites included)

Replaces Approval, Registration No.: HD 60104211 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: 2020-08-12

Date: 2020-08-12

Notified Body

Roland Gruber

TÜV Rheinland LGA Products GmbH

TÜVRheinland

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.

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Doc. 1/3, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60151129 0001
Report No.: 21232416 020

Manufacturer: Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Deutschland

Products included:

- Telescopes, Videoscopes and Fiberscopes
- Electrosurgical Instruments
- Electrosurgical Forceps
- Electrosurgical Hand Pieces
- Electrosurgical Units
- Electrosurgical Electrodes
- Electrosurgical Cables and Adapters, Active Cords
- Peristaltic Pump Units
- Peristaltic Tubing Sets
- Invasive Access Devices
  (which would encompass obturators, sheaths, trocars, bridges and irrigation ports)
- Endoscopy Instruments
  (which would encompass cannulas, injection needles, ballon dilators, adaptors, tubes and non-active instruments)

Date: 2020-08-12

Notified Body

Roland Gruber

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

TÜVRheinland®

Doc. 2/3, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60151129 0001
Report No.: 21232416 020

Manufacturer: Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Deutschland

Products included:

- Working Elements and Inserts
- Bladder Syringes
- Washer-Disinfectors
- Adaptors for Washer-Disinfectors
- Fluid Management Systems used in Endoscopy
- Light Sources

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- sterile Caps

Date: 2020-08-12

Notified Body

Roland Gruber

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

TÜVRheinland®

Doc. 3/3, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60151129 0001
Report No.: 21232416 020

Manufacturer: Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Deutschland

Sites included:

Olympus Winter & Ibe GmbH
Rheinstr. 8
14513 Teltow
Germany

- Design and development, manufacturing of medical devices for electrosurgery and for endoscopic applications

Date: 2020-08-12

Notified Body

Roland Gruber

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2158445-1

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

Scope: Design and Development, Manufacture, Distribution, Service, Quality Assurance, Regulatory Affairs, Planning, Delivery support of Endoscopes, Endotherapy devices, Light Sources, Imaging Processors, Endoscope Position Detecting Units, Electrothermal Cautery Units, Integrated Endosurgery Systems, Endoscopic Regulation/Control Units, Camera Heads/Pumps/Monitors/Recorders for Endoscopy, Electrosurgical Equipment, Capsule Endoscopes and Systems, Laparoscopic Insufflators, Ultrasound Diagnostic Imaging Systems, Disinfecting Units, Ultrasound Surgical Equipment, Ultrasonic surgical system generator, Ultrasonic surgical system transducer, Hard-tissue ultrasonic surgical system holder/tip, Probes and Transducers for Ultrasonic Lithotriptors, Sterile Non Active Instruments used in conjunction with Endoscopes, Sterile Endotherapy Devices used in conjunction with Endoscopes, Sterile Non Active Devices used in conjunction with Medical Ultrasound Diagnostic Imaging Systems and Water Container, Water Supply Tube, Water Feeding valve and Foot Switch for Pump

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150242490-301

Effective date: 2022-03-07

Expiry date: 2024-07-26

Issue date: 2022-03-07

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Ning N. C. Chang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2158445-1

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

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o OLYMPUS MEDICAL SYSTEMS CORP. Ishikawa Office 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507 Japan	Design and Development, Service, Administration, Management, Quality Assurance, Regulatory Affairs, Planning, Delivery support
/02	c/o OLYMPUS MEDICAL SYSTEMS CORP. Shinjuku Monolith Office Shinjuku Monolith, 3-1 Nishishinjuku 2-chome, Shinjuku-ku, Tokyo 163-0914 Japan	Quality Assurance for domestic market
/03	c/o OLYMPUS MEDICAL SYSTEMS CORP. Shirakawa Facility 3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun, Fukushima 961-8061 Japan	Service and Quality Assurance

Report No.: 150242490-301

Effective date: 2022-03-07

Expiry date: 2024-07-26

Issue date: 2022-03-07

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Ning N. C. Chang
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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2158445-1

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

The scope of certification also covers the following:

/04	c/o OLYMPUS MEDICAL SYSTEMS CORP. Aizu Facility 3-1-1 Niiderakita, Aizuwakamatsu-shi, Fukushima 965-8520 Japan	Quality Assurance

Report No.: 150242490-301

Effective date: 2022-03-07

Expiry date: 2024-07-26

Issue date: 2022-03-07

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2158445-1

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

The scope of certification also covers the following:

/05	c/o OLYMPUS MEDICAL SYSTEMS CORP. Aomori Facility 2-248-1 Okkonoki, Kuroishi-shi, Aomori 036-0357 Japan	Quality Assurance of Endoscopes, Endotherapy devices, Light Sources, Imaging Processors, Endoscope Position Detecting Units, Electrothermal Cautery Units, Integrated Endosurgery Systems, Endoscopic Regulation /Control Units, Camera Heads/Pumps/Monitors /Recorders for Endoscopy, Electrosurgical Equipment, Capsule Endoscopes and Systems, Laparoscopic Insufflators, Ultrasound Diagnostic Imaging Systems, Disinfecting Units and Ultrasound Surgical Equipment, Probes and Transducers for Ultrasonic Lithotriptors, Sterile Non Active Instruments used in conjunction with Endoscopes, Sterile Endotherapy Devices used in conjunction with Endoscopes, Sterile Non Active Devices used in conjunction with Medical Ultrasound Diagnostic Imaging Systems and Water Container, Water Supply Tube, Water Feeding valve and Foot Switch for Pump Design and Development of Endotherapy Devices, Sterile Endotherapy Devices used in conjunction with Endoscopes

Report No.: 150242490-301

Effective date: 2022-03-07

Expiry date: 2024-07-26

Issue date: 2022-03-07

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Ning N. C. Chang
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Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02