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

Către: **Agenţia Medicamentului şi Dispozitivelor Medicale**

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat al dispozitivelor medicale nr. 60/05 din 03.05.2023

Solicitantul, **"Endo–Chirurgie" SRL**, cu sediul social în: mun. Chişinău, str. Drumul Viilor, nr. 30/2, ap. (of.) 54, **adresa poştală (de corespondenţă): mun. Chişinău, str. Meşterul Manole, nr. 9**, tel./fax: (022) 23–21–33, (022) 66–72–86, e–mail: **info@akson.md**, solicită înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea şi punerea la dispoziţie pe piaţă a:

- **Unit Car – Richard Wolf**.

Se anexează următoarele acte:

- Declaraţia pe proprie răspundere (RO) – 1 (una) filă.
- Declaraţia de conformitate (EN/DE) – 20 (douăzeci) file.
- Certificatul de conformitate EC (EN) – 3 (trei) file.
- Certificatul de conformitate ISO 13485 (EN) – 2 (două) file.
- Actul prin care producătorul îşi desemnează reprezentantul (EN) – 1 (una) filă.
- Lista dispozitivelor medicale solicitate spre notificare (RO) – 3 (trei) file.
- Copia împuternicirii (RO) – 1 (una) filă.

Data 03.05.2023

Semnătura
Dubalari Pavel, jurisconsult

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "ENDO-CHIRURGIE" IDNO 1009600033240 REPUBLICA MOLDOVA

Tabelul de recepţionare a notificării

(se completează de către Agenţie în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepţionării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenţie (în cazul acceptării recepţionării)	
Numele, prenumele, funcţia persoanei responsabile de recepţionarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Ghereg Victor
Date: 2023.06.11 10:50:24 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2

La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către: **AGENŢIA MEDICAMENTULUI ŞI DISPOZITIVE MEDICALE**

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitantul: **"Endo–Chirurgie" SRL**, cu sediul mun. Chişinău, str. Drumul Viilor, nr. 30/2, ap. (of.) 54, **adresa poştală: mun. Chişinău, str. Meşterul Manole, nr. 9**, declară pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele şi datele furnizate pentru notificarea dispozitivelor medicale:

- **Unit Car – Richard Wolf**.

Sunt autentice şi corespund realităţii.

Dubalari Pavel, jurisconsult

Semnătura _____

Data 03.05.2023

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "ENDO-CHIRURGIE" IDNO 1009600033242 REPUBLICA MOLDOVA

RICHARD WOLF

Original - EU-Konformitätserklärung nach Verordnung (EU) 2017/745 über Medizinprodukte

Translation - EC-Conformity Declaration according to Regulation (EU) 2017/745 on medical devices

Wir

Richard Wolf GmbH
Pforzheimer Straße 32
75438 Knittlingen

Deutschland

SRN: DE-MF-000007048

erklären in alleiniger Verantwortung, dass das/die Medizinprodukt(e) allen anwendbaren Anforderungen der Verordnung (EU) 2017/745 über Medizinprodukte entspricht und wir die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung tragen

We

Richard Wolf GmbH
Pforzheimer Straße 32
75438 Knittlingen

Germany

SRN: DE-MF-000007048

declare under our sole responsibility that the medical device/s meet the provisions of the Regulation EU 2017/745 on medical devices and that we are solely responsible for issuing this Declaration of Conformity

Konformitätsbewertungsverfahren nach:

Artikel 52 Abs. 7, Satz 1 der Verordnung (EU) 2017/745

Conformity assessment procedure according to:

Article 52 (7) sentence 1 of the Regulation EU 2017/745 on medical devices

Gültigkeitsdauer / *Validity:*	13.12.2025
Ort und Datum der Ausstellung / *Place and date of issue:*	Knittlingen, 19.07.2021

	Datum / *Date:*	Unterschrift / *Signature:*
Bereichsleitung Forschung und Entwicklung / *Vice-President Research and Development:*	28.07.2021	Jens Rennert
Abteilungsleitung Zulassung Regulatory Affairs / *Director Global Regulatory Affairs:*	02.08.2021	Ute Greiner
Bereichsleitung Qualität und Regulatorik / *Vice President Global Quality Assurance and Regulatory Affairs:*	[illegible]7.2021	Wulf Brunow

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
S.R.L.
"ENDO-CHIRURGIE"
IDNO 1009600033242
REPUBLICA MOLDOVA

Produktliste / *Product List*

Materialnummer/Typ *Material number/Type*	Produkt- und Handelsname *Product and trade name*	Risikoklasse *Risk class*
85525812	LOGIC HD KAMERAKOPF GREEN *LOGIC HD CAMERA HEAD GREEN*	I

Basis UDI-DI / *Basic UDI-DI:* 405520708102019-0028787HZ

Verwendungszweck

Die Produkte dienen zur Umwandlung eines vom Endoskop erzeugten Bildes des Körperinneren in ein elektronisches Signal für die Weiterleitung an den Kamera Controller sowie zum optischen Filtern des Anregungslichts im Rahmen des Diagnoseverfahren Fluoreszenzbildgebung mit ICG.

Intended use

The products serve to convert an image of the inside of the patient's body generated by an endoscope into an electronic signal which is fed into the camera control unit, and to optically filter the excitation light applied in the fluorescence imaging diagnostic procedure ICG.

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "ENDO-CHIRURGIE" IDNO 1009600033242 REPUBLICA MOLDOVA

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Gültigkeitsdauer / *Validity*: 13.12.2025

Ort und Datum der Ausstellung / *Place and date of issue*: Knittlingen, 21.02.2022

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Bereichsleitung Forschung und Entwicklung / *Vice-President Research and Development*:	21.02.2022	Jens Rennert
Abteilungsleitung Zulassung Regulatory Affairs / *Director Global Regulatory Affairs*:	21.02.22	Ute Greiner
Bereichsleitung Qualität und Regulatorik / *Vice President Global Quality Assurance and Regulatory Affairs*:	21.02.2022	Wulf Brunow

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ENDO-CHIRURGIE" S.R.L. IDNO 1009600033242 REPUBLICA MOLDOVA

Produktliste / *Product List*

Materialnummer/Typ *Material number/Type*	Produkt- und Handelsname *Product and trade name*	Risikoklasse *Risk class*
32116011	GERÄTEWAGEN *UNIT CART*	I
32116012	GERÄTEWAGEN BASIS-ELEK. 100-120VAC *UNIT CART BASE ELECTR. 100-120VAC*	I
32116014	GERÄTEWAGEN BASIS-ELEK. 220-240VAC *UNIT CART BASE ELECTR. 220-240VAC*	I

Basis UDI-DI / *Basic UDI-DI*: 405520711062019-0028609EX

Verwendungszweck

Die Wagen werden zur Lagerung und zum Transport von elektromedizinischen Geräten verwendet. Dabei schaffen sie eine sichere und mobile Arbeitsstation für elektromedizinische Geräte.

Intended use

The products are used for the storage and transport of electromedical devices. They provide a safe mobile workstation for electromedical devices.

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Abteilungsleitung Zulassung Regulatory Affairs / *Director Global Regulatory Affairs*:	21.02.2022	Ute Greiner
Bereichsleitung Qualität und Regulatorik / *Vice President Global Quality Assurance and Regulatory Affairs*:	21.02.2022	Wulf Brunow

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "ENDO-CHIRURGIE" IDNO 1009600033242 REPUBLICA MOLDOVA

Produktliste / *Product List*

Materialnummer/Typ *Material number/Type*	Produkt- und Handelsname *Product and trade name*	Risikoklasse *Risk class*
32116013	GERÄTEWAGEN PREMIUM-ELEK. 100-120VAC *UNIT CART PREMIUM-ELEC. 100-120VAC*	I
32116015	GERÄTEWAGEN PREMIUM-ELEK.220-230VAC *UNIT CART PREMIUM-ELEC. 220-230VAC*	I

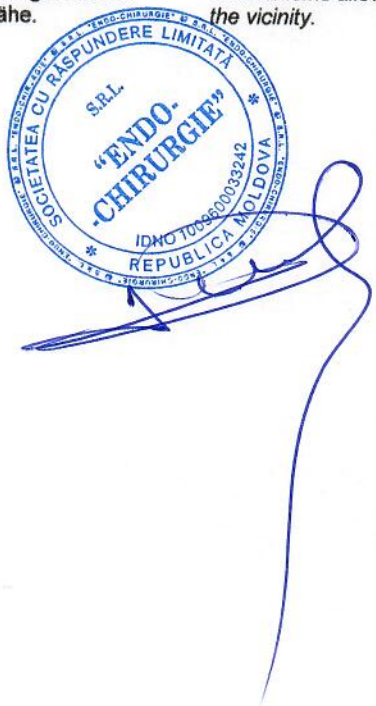
Basis UDI-DI / *Basic UDI-DI*: 405520711062019-0028611EJ

Verwendungszweck

Die Produkte dienen zur Lagerung und zum Transport von elektromedizinischen Geräten und ermöglichen durch elektrische Sicherheitsmechanismen eine elektrisch gesicherte Verwendung von Medizingeräten in räumlicher Nähe.

Intended use

The products are used for the storage and transport of electromedical devices and thanks to their electrical safety mechanisms allow electrically safe use of medical devices in the vicinity.



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Artikel 52 Abs. 7, Satz 1 der Verordnung (EU) 2017/745

Conformity assessment procedure according to:

Article 52 (7) sentence 1 of the Regulation EU 2017/745 on medical devices

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Ort und Datum der Ausstellung / *Place and date of issue*: Knittlingen, 19.07.2021

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Bereichsleitung Forschung und Entwicklung / *Vice-President Research and Development*:	28.07.2021	Jens Rennert
Abteilungsleitung Zulassung Regulatory Affairs / *Director Global Regulatory Affairs*:	02.08.2021	Ute Greiner
Bereichsleitung Qualität und Regulatorik / *Vice President Global Quality Assurance and Regulatory Affairs*:	30.07.2021	Wulf Brunow

S.R.L. „ENDO-CHIRURGIE"
SOCIETATEA CU RĂSPUNDERE LIMITATĂ
IDNO 1006600033242
REPUBLICA MOLDOVA

Produktliste / *Product List*

Materialnummer/Typ *Material number/Type*	Produkt- und Handelsname *Product and trade name*	Risikoklasse *Risk class*
5514101	PERFORMANCE HD KAMERA CONTROLLER *PERFORMANCE HD CAMERA CONTROLLER*	I
5521101	FLEX HD KAMERA CONTROLLER *FLEX HD CAMERA CONTROLLER*	I
5522101	D KAMERA CONTROLLER *D CAMERA CONTROLLER*	I
5525101	LOGIC HD KAMERA CONTROLLER *LOGIC HD CAMERA CONTROLLER*	I
5525105	LOGIC HD KAMERA CONTROLLER *LOGIC HD CAMERA CONTROLLER*	I
5525106	LOGIC HD KAMERA CONTROLLER *LOGIC HD CAMERA CONTROLLER*	I
5525107	LOGIC HD KAMERA CONTROLLER *LOGIC HD CAMERA CONTROLLER*	I
5525108	LOGIC HD KAMERA CONTROLLER *LOGIC HD CAMERA CONTROLLER*	I
5525201	LOGIC HD LITE KAMERA CONTROLLER *LOGIC HD LITE CAMERA CONTROLLER*	I
5525301	LOGIC 4K KAMERA CONTROLLER *LOGIC 4K CAMERA CONTROLLER*	I

Basis UDI-DI /
Basic UDI-DI: 405520724072019-0017684N6

Verwendungszweck

Die Produkte dienen zur Darstellung des über ein starres oder flexibles Endoskop erzeugten Bildes des Körperinneren.

Intended use

The products serve to display an image of the inside of the body generated via a rigid or flexible endoscope.

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Translation - EC-Conformity Declaration according to Regulation (EU) 2017/745 on medical devices

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SRN: DE-MF-000007048

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Artikel 52 Abs. 7, Satz 1 der Verordnung (EU) 2017/745

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Gültigkeitsdauer / *Validity:* 13.12.2025

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	Datum / *Date:*	Unterschrift / *Signature:*
Bereichsleitung Forschung und Entwicklung / *Vice-President Research and Development:*	28.07.2021	Jens Rennert
Abteilungsleitung Zulassung Regulatory Affairs / *Director Global Regulatory Affairs:*	02.08.2021	Ute Greiner
Bereichsleitung Qualität und Regulatorik / *Vice President Global Quality Assurance and Regulatory Affairs:*	30.07.2021	Wulf Brunow

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "ENDO-CHIRURGIE" IDNO 1009600033242 REPUBLICA MOLDOVA

Produktliste / *Product List*

Materialnummer/Typ *Material number/Type*	Produkt- und Handelsname *Product and trade name*	Risikoklasse *Risk class*
5514901	PERFORMANCE KAMERAKOPF KABEL 4M *PERFORMANCE CAMERA HEAD CABLE 4M*	I
5514961	PERFORMANCE KAMERAKOPF KABEL 4M *PERFORMANCE CAMERA HEAD CABLE 4M*	I
5521902	FLEX HD KAMERAKOPF KABEL 2,5M *FLEX HD CAMERA HEAD CABLE 2,5M*	I
5525933	LOGIC HD PENDUAL-KAMERAKOPF KABEL 3M *LOGIC HD PENDUAL CAMERA HEAD CABLE 3M*	I
85525902	LOGIC HD KAMERAKOPF KABEL 3M *LOGIC HD CAMERA HEAD CABLE 3M*	I
85525922	LOGIC HD KAMERAKOPF KABEL 3M *LOGIC HD CAMERA HEAD CABLE 3M*	I
85525942	LOGIC 4K KAMERAKOPF *LOGIC 4K CAMERA HEAD*	I

Basis UDI-DI / *Basic UDI-DI*: 405520724072019-0017775NA

Verwendungszweck

Die Produkte dienen zur Umwandlung eines vom Endoskop erzeugten Bildes des Körperinneren in ein elektronisches Signal für die Weiterleitung an den Kameracontroller.

Intended use

The products serve to convert an image of the inside of the patient's body generated by an endoscope into an electronic signal which is fed to the camera control unit.

RICHARD WOLF

Original - EU-Konformitätserklärung nach Verordnung (EU) 2017/745 über Medizinprodukte

Translation - EC-Conformity Declaration according to Regulation (EU) 2017/745 on medical devices

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Richard Wolf GmbH
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75438 Knittlingen

Deutschland

SRN: DE-MF-000007048

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Konformitätsbewertungsverfahren nach:

Artikel 52 Abs. 7, Satz 1 der Verordnung (EU) 2017/745

Conformity assessment procedure according to:

Article 52 (7) sentence 1 of the Regulation EU 2017/745 on medical devices

Gültigkeitsdauer / *Validity:* 13.12.2025

Ort und Datum der Ausstellung / *Place and date of issue* Knittlingen, 19.07.2021

	Datum / *Date*	Unterschrift / *Signature*
Bereichsleitung Forschung und Entwicklung / *Vice-President Research and Development:*	28.07.2021	Jens Rennert
Abteilungsleitung Zulassung Regulatory Affairs / *Director Global Regulatory Affairs:*	04.08.2021	Ute Greiner
Bereichsleitung Qualität und Regulatorik / *Vice President Global Quality Assurance and Regulatory Affairs:*	30.07.2021	Wulf Brunow

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "ENDO-CHIRURGIE" IDNO 1009800033242 REPUBLICA MOLDOVA

Produktliste / *Product List*

Materialnummer/Typ *Material number/Type*	Produkt- und Handelsname *Product and trade name*	Risikoklasse *Risk class*
5525833	LOGIC HD PENDUAL-KAMERAKOPF BLUE *LOGIC HD PENDUAL CAMERA HEAD BLUE*	I

Basis UDI-DI / *Basic UDI-DI*: 4055207240720l9-0017879NP

Verwendungszweck

Die Produkte dienen zur Umwandlung eines vom Endoskop erzeugten Bildes des Körperinneren in ein elektronisches Signal für die Weiterleitung an den Kamera Controller sowie zum optischen Filtern des blauen Anregungslichts im Rahmen des Diagnoseverfahren Photodynamische Diagnose PDD.

Intended use

The products serve to convert an image of the inside of the patient's body generated by an endoscope into an electronic signal which is fed to the camera control unit and to optically filter the blue excitation light within the scope of the PDD (photodynamic diagnose) diagnostic procedure.

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Translation - EC-Conformity Declaration according to Regulation (EU) 2017/745 on medical devices

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Bereichsleitung Qualität und Regulatorik / *Vice President Global Quality Assurance and Regulatory Affairs:*	30.07.2021	Wulf Brunow

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "ENDO-CHIRURGIE" IDNO 1009600033242 REPUBLICA MOLDOVA

Produktliste / *Product List*

Materialnummer/Typ *Material number/Type*	Produkt- und Handelsname *Product and trade name*	Risikoklasse *Risk class*
5165001	LICHTQUELLE LED BLUE *LIGHT SOURCE LED BLUE*	I

Basis UDI-DI / *Basic UDI-DI:* 405520725102019-0017725FN

Verwendungszweck

Die Produkte dienen zur Bereitstellung von Weißlicht und Blaulicht für diagnostische und therapeutische Anwendungen speziell in der Endoskopie.

Intended use

The products serve to provide white light and blue light for diagnostic and therapeutic applications particularly in endoscopy

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Abteilungsleitung Zulassung Regulatory Affairs / *Director Global Regulatory Affairs:*	02.08.2021	Ute Greiner
Bereichsleitung Qualität und Regulatorik / *Vice President Global Quality Assurance and Regulatory Affairs:*	30.07.2021	Wulf Brunow

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "ENDO-CHIRURGIE" IDNO 1009600033242 REPUBLICA MOLDOVA

Produktliste / *Product List*

Materialnummer/Typ *Material number/Type*	Produkt- und Handelsname *Product and trade name*	Risikoklasse *Risk class*
5165002	LICHTQUELLE LED GREEN *LIGHT SOURCE LED GREEN*	I

Basis UDI-DI / *Basic UDI-DI:* 405520725102019-0028045FB

Verwendungszweck

Die Produkte dienen zur Bereitstellung von Weißlicht und nah-infrarotem Licht für diagnostische und therapeutische Anwendungen speziell in der Endoskopie.

Intended use

The products serve to provide white light and near-infrared light for diagnostic and therapeutic applications particularly in endoscopy.

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ENDO-CHIRURGIE" S.R.L. IDNO 1009600033242 REPUBLICA MOLDOVA

Original - EU-Konformitätserklärung nach Verordnung (EU) 2017/745 über Medizinprodukte

Translation - EC-Conformity Declaration according to Regulation (EU) 2017/745 on medical devices

Wir

Richard Wolf GmbH
Pforzheimer Straße 32
75438 Knittlingen

Deutschland

SRN: DE-MF-000007048

erklären in alleiniger Verantwortung, dass das/die Medizinprodukt(e) allen anwendbaren Anforderungen der Verordnung (EU) 2017/745 über Medizinprodukte entspricht und wir die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung tragen

We

Richard Wolf GmbH
Pforzheimer Straße 32
75438 Knittlingen

Germany

SRN: DE-MF-000007048

declare under our sole responsibility that the medical device/s meet the provisions of the Regulation EU 2017/745 on medical devices and that we are solely responsible for issuing this Declaration of Conformity

Konformitätsbewertungsverfahren nach:

Artikel 52 Abs. 7, Satz 1 der Verordnung (EU) 2017/745

Conformity assessment procedure according to:

Article 52 (7) sentence 1 of the Regulation EU 2017/745 on medical devices

Gültigkeitsdauer / *Validity:* 13.12.2025

Ort und Datum der Ausstellung / *Place and date of issue:* Knittlingen, 19.07.2021

	Datum / *Date:*	Unterschrift / *Signature:*
Bereichsleitung Forschung und Entwicklung / *Vice-President Research and Development:*	28.07.2021	Jens Rennert
Abteilungsleitung Zulassung Regulatory Affairs / *Director Global Regulatory Affairs:*	02.08.2021	Ute Greiner
Bereichsleitung Qualität und Regulatorik / *Vice President Global Quality Assurance and Regulatory Affairs:*	30.07.2021	Wulf Brunow

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "ENDO-CHIRURGIE" IDNO 1006600033242 REPUBLICA MOLDOVA

Produktliste / *Product List*

Materialnummer/Typ *Material number/Type*	Produkt- und Handelsname *Product and trade name*	Risikoklasse *Risk class*
5160001	LICHTQUELLE LED 1.1 76W *LIGHT SOURCE LED 1.1 76W*	I
5161001	LICHTQUELLE LED 1.2 76W *LIGHT SOURCE LED 1.2 76W*	I
5163001	LICHTQUELLE LED 2.1 80W *LIGHT SOURCE LED 2.1 80W*	I
5164001	LICHTQUELLE LED 2.2 80W *LIGHT SOURCE LED 2.2 80W*	I
5166001	LICHTQUELLE FLEX LED 42W *LIGHT SOURCE FLEX LED 42W*	I

Basis UDI-DI / *Basic UDI-DI*: 405520727052019-0017664PT

Verwendungszweck

Die Produkte dienen zur Lichtabgabe im sichtbaren Bereich für die Ausleuchtung des Körperinneren.

Intended use

The products serve to emit light in the visual range to illuminate the inside of the patient's body.

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "ENDO-CHIRURGIE" IDNO 1009600033242 REPUBLICA MOLDOVA

RICHARD WOLF

Original - EU-Konformitätserklärung nach Verordnung (EU) 2017/745 über Medizinprodukte

Translation - EC-Conformity Declaration according to Regulation (EU) 2017/745 on medical devices

Wir

Richard Wolf GmbH
Pforzheimer Straße 32
75438 Knittlingen

Deutschland

SRN: DE-MF-000007048

erklären in alleiniger Verantwortung, dass das/die Medizinprodukt(e) allen anwendbaren Anforderungen der Verordnung (EU) 2017/745 über Medizinprodukte entspricht und wir die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung tragen

We

Richard Wolf GmbH
Pforzheimer Straße 32
75438 Knittlingen

Germany

SRN: DE-MF-000007048

declare under our sole responsibility that the medical device/s meet the provisions of the Regulation EU 2017/745 on medical devices and that we are solely responsible for issuing this Declaration of Conformity

Konformitätsbewertungsverfahren nach:

Artikel 52 Abs. 7, Satz 1 der Verordnung (EU) 2017/745

Conformity assessment procedure according to:

Article 52 (7) sentence 1 of the Regulation EU 2017/745 on medical devices

Gültigkeitsdauer / *Validity*: 13.12.2025

Ort und Datum der Ausstellung / *Place and date of issue*: Knittlingen, 19.07.2021

	Datum / *Date*:	Unterschrift / *Signature*:
Bereichsleitung Forschung und Entwicklung / *Vice-President Research and Development*:	28.07.2021	Jens Rennert
Abteilungsleitung Zulassung Regulatory Affairs / *Director Global Regulatory Affairs*:	02.08.2021	Ute Greiner
Bereichsleitung Qualität und Regulatorik / *Vice President Global Quality Assurance and Regulatory Affairs*:	30.07.2021	Wulf Brunow

S.R.L. "ENDO-CHIRURGIE" SOCIETATEA CU RĂSPUNDERE LIMITATĂ IDNO 1009600033242 REPUBLICA MOLDOVA

900,124a

DE / EN

Produktliste / *Product List*

Materialnummer/Typ *Material number/Type*	Produkt- und Handelsname *Product and trade name*	Risikoklasse *Risk class*
5531001	EPIC 3DHD KAMERA SYSTEM *EPIC 3DHD CAMERA SYSTEM*	I

Basis UDI-DI / *Basic UDI-DI:* 405520727052019-0028582QA

Verwendungszweck

Die Produkte dienen zur Darstellung des über ein starres oder flexibles Stereoendoskop erzeugten Bildes des Körperinneren.

Intended use

The products serve to visualize the image of the inside of the body generated via rigid or flexible stereo endoscope.

SOCIETATEA CU RASPUNDERE LIMITATĂ S.R.L. "ENDO-CHIRURGIE" IDNO 1006600033242 REPUBLICA MOLDOVA

EC CERTIFICATE

for the Quality Assurance System

according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

Richard Wolf GmbH

Pforzheimer Straße 32, 75438 Knittlingen, Germany

Certified location:

Pforzheimer Straße 32, 75438 Knittlingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50593-Z7-00, the decision dated 2020-04-01 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2020-04-01 to 2024-05-26

Registration No.: 50593-16-05

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-04-01
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Certificate No. 50593-16-05

Valid from 2020-04-01 to 2024-05-26

Revision status of the annex: 0 dated 2020-04-01

Devices/device categories included in the certificate:

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- Endoscopic suction valve, single-use, sterile
- Suction system filter, plume particulate
- Suction/irrigation tubing, single use

Class II a:

- Basic endotracheal tube, reusable
- Basic roller pump
- Bone cutting forceps
- Bone graft funnel
- Bronchoscopy tube
- Cannulated surgical drill bit, reusable
- Endoscope assembly adaptor
- Endoscope sheath, reusable
- Endoscopic electrosurgical handpiece/electrode, bipolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic insufflation tubing set, single-use
- Endoscopic insufflation tubing set, sterile, reusable
- Flexible fibreoptic cystourethroscope
- Flexible fibreoptic hysteroscope
- Flexible fibreoptic nasopharyngoscope
- Flexible fibreoptic ureterorenoscope
- Flexible video bronchoscope, reusable
- Flexible video cystoscope, reusable
- Flexible video ureterorenoscope, reusable
- Fluted surgical drill bit, reusable
- General-purpose endoscopic needle, reusable
- General-purpose endoscopic needle, single-use
- Haemorrhoid ligator
- High-pressure medical gas tubing
- Laparoscopic access cannula, reusable
- Laparoscopic multi-instrument access port, reusable
- Laparoscopic multi-instrument access port, single-use
- Laser fibre
- Line-powered surgical power tool system motor
- Medical air low pressure tubing
- Microbial medical gas filter, sterile, single-use
- Operating room audiovisual data/device management system application software
- Orthopaedic bur, reusable
- Orthopaedic bur, single-use
- Resectoscope
- Rigid bronchoscope
- Rigid cystourethroscope
- Rigid endoscope telescope
- Rigid endoscopic grasping forceps, reusable
- Rigid optical hysteroscope
- Rigid intubation laryngoscope, reusable

Annex to the EC Certificate No. 50593-16-05

Valid from 2020-04-01 to 2024-05-26

Revision status of the annex: 0 dated 2020-04-01

Devices/device categories included in the certificate:

- Rigid mediastinoscope
- Rigid nephroscope
- Rigid optical laparoscope
- Rigid ureterorenoscope
- Spinal needle, single-use
- Spring-loaded pneumoperitoneum needle, reusable
- Surgical drill guide, reusable
- Surgical fluid/smoke waste management system suction unit
- Surgical guillotine
- Surgical irrigation tubing set, reusable
- Surgical irrigation tubing set, single-use
- Surgical irrigation/aspiration handpiece, reusable
- Surgical irrigation/aspiration tubing set
- Surgical power tool system control unit, line-powered
- Tissue extraction bag
- Tissue morcellation system
- Tissue morcellation system handpiece, line-powered
- Uterine manipulator cervical cup/transilluminator
- Uterine manipulator, reusable
- Uterine probe

Class II b:

- Electrosurgical system generator
- Endoscopic electrosurgical electrode, bipolar, reusable
- Endoscopic electrosurgical electrode, bipolar, single-use, sterile
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic electrosurgical electrode, monopolar, single-use
- Endoscopic electrosurgical handpiece/electrode, bipolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
- General/multiple surgical diode Laser system
- Hysteroscopic irrigation/insufflation system
- Laparoscopic insufflator
- Laser lithotripsy system
- Operating room audiovisual data/device management system application software
- Piezoelectric lithotripsy system
- Soft-tissue/mesh anchor, non-bioabsorbable
- Ultrasonic lithotripsy system
- Electromechanical orthopaedic extracorporeal shock wave therapy system

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-01
Notified Body ID-number: 0124

CERTIFICATE

EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

Richard Wolf GmbH

Scope of certification:

Design and development, production, distribution, installation and service of systems, active medical devices (sterile, non-sterile), non-active medical devices (sterile, non-sterile) for human medicine, in particular for endoscopy and extracorporeal shockwave application.
Design and development, production, and distribution of non-active implants in urology and surgery as well as accessories for processing (cleaning, disinfection, sterilization)

Certified location:

Pforzheimer Straße 32, 75438 Knittlingen, Germany

(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50593-R2-00.

Certificate registration no.:	50593-14-02	Certificate valid from:	2021-11-29
Validity of previous certificate:	2021-11-28	Certificate valid to:	2024-11-28

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-11-29

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16029-08-00

Annex to the Certificate No. 50593-14-02

Revision status: 0

valid from 2021-11-29 to 2024-11-28

The following locations / companies belong to the certificate above:

	Headquarter	Certified location	Scope of certification
	Richard Wolf GmbH	Pforzheimer Straße 32 75438 Knittlingen Germany	see page 1
	at the following locations / at the companies at the following locations		**Scope of certification**
1.	Richard Wolf GmbH	Reuchlinstraße 10-11 10553 Berlin Germany	Manufacture of flexible and rigid endoscopes

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-11-29

RICHARD WOLF

spirit of excellence

TO WHOM IT MAY CONCERN

Knittlingen, December 19th, 2022

AUTHORIZATION LETTER

We, **Richard Wolf GmbH, Pforzheimer Str. 32, 75438 Knittlingen, Germany,** a manufacturer and supplier of Medical Endoscopic Equipment, duly organized under the laws of Germany, hereby declare that the company

Endo-Chirurgie LTD
9 Mesterul Manole str., MD-2023
Chisinau
REPUBLIC OF MOLDOVA

is authorized to sell and distribute Richard Wolf Medical Endoscopic Equipment, except Spine Surgery Systems, in the territory of Moldova. The above company is also entitled to participate at related public tenders for the stated products.

Furthermore, the company is able to organize the commissioning, functional testing as well as warranty and post-warranty service procedure for the related products in cooperation with and on behalf of the Richard Wolf GmbH.

We hereby grant our full warranty for the Richard Wolf Medical Endoscopic Equipment offered by the above firm in accordance with our General Terms and Conditions of Business.

This authorization is effective immediately and valid until December 31, 2023.

Yours faithfully
RICHARD WOLF GMBH

RICHARD WOLF
GmbH
75438 KNITTLINGEN

Jürgen Steinbeck
Co-CEO

Volker Maute
Vice President Sales, Service & Marketing

SOCIETATEA CU RASPUNDERE LIMITATA S.R.L. "ENDO-CHIRURGIE" IDNO 1006600035242 REPUBLICA MOLDOVA

Lista dispozitivelor medicale solicitate spre notificare					
Nr.	**Numărul de catalog (referinţă)***	**Denumire generică (denumirea dispozitivului)**	**Denumire comercială (brand)***	**Modelul**	**Cod GMDN***
1	55253011	4K camera controller	ENDOCAM Logic 4K camera controller bndl	ENDOCAM Logic 4K	
2	55251011	HD camera controller 2x HDMI out	ENDOCAM Logic HD controller bndl	ENDOCAM Logic HD	
3	55251051	HD camera controller 2x HDMI out / 2x 3G-SDI out	ENDOCAM Logic HD controller bndl	ENDOCAM Logic HD	
4	55251061	HD camera controller 2x HDMI out / 2x 3G-SDI out / PIP in	ENDOCAM Logic HD controller bndl	ENDOCAM Logic HD	
5	85525942	3-chip 4K camera head	ENDOCAM Logic 4K camera head	ENDOCAM Logic 4K camera head	
6	85261144	Lentile f = 14 mm	RIWO lens	RIWO lens	
7	85261244	Lentile f = 24 mm	RIWO lens	RIWO lens	
8	85261504	Lentile f = 13-29 mm	RIWO zoom lens	RIWO zoom lens	
9	5257141	angular lens f = 14 mm	RIWO angular lens	RIWO angular lens	
10	5257171	angular lens f = 17 mm	RIWO angular lens	RIWO angular lens	
11	85525922	3-chip HD camera head	ENDOCAM Logic HD camera head	ENDOCAM Logic HD camera head	
12	85525902	1-chip HD camera head	ENDOCAM Logic HD camera head	ENDOCAM Logic HD camera head	

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "ENDO-CHIRURGIE" IDNO 1009600033242 REPUBLICA MOLDOVA

13	85525812	2-chip HD camera head green	Logic HD camera head green	Camera head green for the NIR/ICG Application	
14	5525833	1-chip HD camera head blue	Pendual camera head blue	Pendual camera head blue	
15	5525933	1-chip HD camera head	Pendual camera head	Pendual camera head	
16	55252011	HD Lite camera controller	ENDOCAM Logic HD Lite camera controller bndl	ENDOCAM Logic HD Lite Camera controller	
17	55211011	Camera controller	ENDOCAM Flex HD camera controller	ENDOCAM Flex HD camera controller	
18	5521902	1-chip HD camera head	ENDOCAM Flex HD camera head	ENDOCAM Flex HD camera head	
19	55310012	3DHD camera controller incl. camera head	ENDOCAM Epic 3DHD camera system bndl	ENDOCAM Epic 3DHD camera system bndl	
20	51640011	LED light source	Light source ENDOLIGHT LED 2.2 bndl	LENDOLIGHT LED 2.2	
21	51630011	LED light source	Light source ENDOLIGHT LED 2.1	ENDOLIGHT LED 2.1	
22	51650021	LED light source	Light source LEDgreen bndl	ENDOLIGHT LEDgreen	
23	51650011	LED light source	Light source ENDOLIGHT LED blue bndl	ENDOLIGHT LEDblue	
24	51610011	LED light source	Light source ENDOLIGHT LED 1.2 bndl	ENDOLIGHT LED 1.2	
25	51600011	LED light source	Light source ENDOLIGHT LED 1.1 bndl	ENDOLIGHT LED 1.1	

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "ENDO-CHIRURGIE" IDNO 1009600033242 REPUBLICA MOLDOVA

26	51660011	LED light source	Light source ENDOLIGHT Flex LED bndl	ENDOLIGHT Flex LED	
27	32116015	Troleu cu cu transformator de izolare integrat	RIWOmobil with premium electrics	RIWOmobil	
28	32116014	Troleu cu electricitate de bază	RIWOmobil with baseline electrics	RIWOmobil	

"Endo–Chirurgie" SRL

Data 03.05.2023 Semnătură

Dubalari Pavel, jurisconsult

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "ENDO-CHIRURGIE" IDNO 1009600033242 REPUBLICA MOLDOVA

S.C. "Endo–Chirurgie" S.R.L.
Codul fiscal: **1009600033242**
Adresa postală: **mun. Chișinău, str. Mesterul Manole nr. 9.**
Telefon/Fax: **(022) 23–21–33, (022) 66–72–86**
E–mail: **info@akson.md**

NR. 163/09 din 05/09/2022

ÎMPUTERNICIRE

Subscrisa, **"Endo–Chirurgie" SRL**, cu sediul în Republica Moldova, mun. Chișinău, str. Drumul Viilor, nr. 30/2, ap. (of) 54, MD–2021, IDNO: 1009600033242, reprezentată de **GHEREG Victor**, în calitate de administrator, prin prezenta îl împuternicesc pe domnul **DUBALARI Pavel**, IDNP 2001003326049, angajat în cadrul companiei în calitate de jurisconsult, pentru ca în numele meu și în contul societății sus menționate să îndeplinească toate formalitățile necesare în raport cu persoanele fizice, juridice, autorităților statului, inclusiv Agenția Medicamentului și Dispozitivelor Medicale din Republica Moldova, în vederea efectuării tuturor acțiunilor necesare în cadrul **procedurilor de înregistrare (notificare) a dispozitivelor medicale**, semnătura sa fiindu–mi opozabilă atât mie cât și terților.

Orice altă operațiune nemenționată expres dar necesară îndeplinirii prezentului mandat va avea acordul meu.

Împuternicirea este valabilă pînă la data de 31.12.2023.

Administrator,
.....