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. 59/05 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:

- **Insuflator CO2 – Richard Wolf**.

Se anexează următoarele acte:

- Declaraţia pe proprie răspundere (RO) – 1 (una) filă.
- Declaraţia de conformitate (EN/DE) – 10 (zece) 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) – 2 (două) file.
- Copia împuternicirii (RO) – 1 (una) filă.

Data 03.05.2023

Semnătura _____
Dubalari Pavel, jurisconsult

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	

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:

- **Insuflator CO2 – Richard Wolf**.

Sunt autentice şi corespund realităţii.

Dubalari Pavel, jurisconsult

Semnătura _____

Data 03.05.2023

Konformitätserklärung nach Richtlinie 93/42/EWG für Medizinprodukte

Conformity Declaration according to Medical Device Directive 93/42/EEC

Wir

RICHARD WOLF GMBH
Pforzheimer Straße 32
75438 Knittlingen
Deutschland

erklären in alleiniger Verantwortung, dass das/die Medizinprodukt/e

We

RICHARD WOLF GMBH
Pforzheimer Straße 32
75438 Knittlingen
Germany

declare under our sole responsibility that the medical device/s

Bezeichnung:
MOTORHANDGRIFF MAX. 6000U/MIN

designation:
MOTOR HANDPIECE MAX. 6000RPM

Typ:

type:

8564.021

allen anwendbaren Anforderungen der Richtlinie 93/42/EWG über Medizinprodukte entspricht.

meets all applicable requirements of the Medical Device Directive 93/42/EEC.

Konformitätsbewertungsverfahren Anhang:

☒ II, ☐ III, ☐ IV, ☐ V, ☐ VI, ☐ VII

Conformity assessment procedure annex:

Dies ist erkennbar an der nachfolgend aufgeführten CE Kennzeichnung des Produkts und / oder der dem Produkt beigefügten Informationen.

This is visible by one of the following CE markings on the product and / or the enclosed information.

☐ CE / CE

☒ CE 0124 / CE 0124

DEKRA Certification GmbH
Handwerkstraße 15, 70565 Stuttgart

Gültigkeitsdauer / *Validity:* 2024-05-26

Ort und Datum der Ausstellung: Knittlingen, 2020-07-16

Bereichsleitung Forschung und Entwicklung *Vice-President Research and Development*	17.07.2020	J. Rennert	
Abteilungsleitung Zulassung Regulatory Affairs *Senior Director Global Regulatory Affairs*	16.07.2020	A. Völker	
Abteilungsleitung QM & QA *Director QM & QA*	20.07.2020	W. Brunow	
	Datum / *Date*	Name	Unterschrift / *Signature*

S.R.L. "ENDO-CHIRURGIE" IDNO 1009600033242 REPUBLICA MOLDOVA

RICHARD WOLF

Konformitätserklärung nach Richtlinie 93/42/EWG für Medizinprodukte

Conformity Declaration according to Medical Device Directive 93/42/EEC

Wir	*We*
RICHARD WOLF GMBH Pforzheimer Straße 32 75438 Knittlingen Deutschland	*RICHARD WOLF GMBH* *Pforzheimer Straße 32* *75438 Knittlingen* *Germany*
erklären in alleiniger Verantwortung, dass das/die Medizinprodukt/e	*declare under our sole responsibility that the medical device/s*

Bezeichnung: / *designation:*
* siehe Anlage / * see attached list

Typ: / *type:*

2235001 2235021 2235601 2235621

allen anwendbaren Anforderungen der Richtlinie 93/42/EWG über Medizinprodukte entspricht. / *meets all applicable requirements of the Medical Device Directive 93/42/EEC.*

Konformitätsbewertungsverfahren Anhang: / *Conformity assessment procedure annex:*

☒ II, ☐ III, ☐ IV, ☐ V, ☐ VI, ☐ VII

Dies ist erkennbar an der nachfolgend aufgeführten CE Kennzeichnung des Produkts und / oder der dem Produkt beigefügten Informationen. / *This is visible by one of the following CE markings on the product and / or the enclosed information.*

☐ CE / CE

☒ CE 0124 / CE 0124

DEKRA Certification GmbH
Handwerkstraße 15, 70565 Stuttgart

Gültigkeitsdauer / *Validity:* 2024-05-26

Ort und Datum der Ausstellung: Knittlingen, 2020-05-15

Bereichsleitung Forschung und Entwicklung *Vice-President Research and Development*	: 07.10.2020	J. Rennert	
Abteilungsleitung Zulassung Regulatory Affairs *Senior Director Global Regulatory Affairs*	: 02.10.2020	A. Völker	
Abteilungsleitung QM & QA *Director QM & QA*	08.10.2020	W. Brunow	
	Datum / *Date*	Name	Unterschrift / *Signature*

SOCIETATEA CU RASPUNDERE LIMITATA S.R.L. "ENDO-CHIRURGIE" IDNO 1009600033242 REPUBLICA MOLDOVA

Typ/*Type*/ Modèle/Tipo	Bezeichnung	*Designation*	Désignation	Designación
2235001	INSUFFLATOR 45 BASIC FR 45L/MIN	*INSUFFLATOR 45 BASIC FR 45L/MIN*	INSUFFLATEUR 45 BASIC DÉBIT 45L/MIN	INSUFLADOR 45 BASIC CAUDAL 45L/MIN
2235021	INSUFFLATOR 45 HEAT FR 45L/MIN	*INSUFFLATOR 45 HEAT FR 45L/MIN*	INSUFFLATEUR 45 HEAT DÉBIT 45L/MIN	INSUFLADOR 45 HEAT CAUDAL 45L/MIN
2235601	INSUFFLATOR 45 BASIC FR 45L/MIN	*INSUFFLATOR 45 BASIC FR 45L/MIN*	INSUFFLATEUR 45 BASIC DÉBIT 45L/MIN	INSUFLADOR 45 BASIC CAUDAL 45L/MIN
2235621	INSUFFLATOR 45 HEAT FR 45L/MIN	INSUFFLATOR 45 HEAT FR 45L/MIN	INSUFFLATEUR 45 HEAT DÉBIT 45L/MIN	INSUFLADOR 45 HEAT CAUDAL 45L/MIN

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

RICHARD WOLF

Konformitätserklärung nach Richtlinie 93/42/EWG für Medizinprodukte

Conformity Declaration according to Medical Device Directive 93/42/EEC

Wir	*We*
RICHARD WOLF GMBH Pforzheimer Straße 32 75438 Knittlingen Deutschland	*RICHARD WOLF GMBH* *Pforzheimer Straße 32* *75438 Knittlingen* *Germany*
erklären in alleiniger Verantwortung, dass das/die Medizinprodukt/e	*declare under our sole responsibility that the medical device/s*

Bezeichnung:	*designation:*
INSUFFLATOR 45 EVAC FR 45L/MIN	INSUFFLATOR 45 EVAC FR 45L/MIN
INSUFFLATOR 45 EVAC + HEAT FR 45L/MIN	INSUFFLATOR 45 EVAC + HEAT FR 45L/MIN
INSUFFLATOR 45 EVAC FR 45L/MIN	INSUFFLATOR 45 EVAC FR 45L/MIN
INSUFFLATOR 45 EVAC + HEAT FR 45L/MIN	INSUFFLATOR 45 EVAC + HEAT FR 45L/MIN
Typ:	*type:*
2235011 2235031	**2235611 2235631**

allen anwendbaren Anforderungen der Richtlinie 93/42/EWG über Medizinprodukte entspricht.	*meets all applicable requirements of the Medical Device Directive 93/42/EEC.*
Konformitätsbewertungsverfahren Anhang:	*Conformity assessment procedure annex:*
☒ II, ☐ III, ☐ IV,	☐ V, ☐ VI, ☐ VII
Dies ist erkennbar an der nachfolgend aufgeführten CE Kennzeichnung des Produkts und / oder der dem Produkt beigefügten Informationen.	*This is visible by one of the following CE markings on the product and / or the enclosed information.*
☐ CE / CE	☒ CE 0124 / CE 0124
	DEKRA Certification GmbH Handwerkstraße 15, 70565 Stuttgart

Gültigkeitsdauer / *Validity:* 2024-05-26

Ort und Datum der Ausstellung: Knittlingen, 2020-09-30

Bereichsleitung Forschung und Entwicklung *Vice-President Research and Development*	: 07.10.2020	J. Rennert	
Abteilungsleitung Zulassung Regulatory Affairs *Senior Director Global Regulatory Affairs*	: 02.10.20	A. Völker	
Abteilungsleitung QM & QA *Director QM & QA*	08.10.2020	W. Brunow	
	Datum / *Date*	Name	Unterschrift / *Signature*

S.R.L. "ENDO-CHIRURGIE" IDNO 1008600033242 MOLDOVA

503,022f

RICHARD WOLF

Konformitätserklärung nach Richtlinie 93/42/EWG für Medizinprodukte

Conformity Declaration according to Medical Device Directive 93/42/EEC

Wir	*We*
RICHARD WOLF GMBH Pforzheimer Straße 32 75438 Knittlingen Deutschland	*RICHARD WOLF GMBH* *Pforzheimer Straße 32* *75438 Knittlingen* *Germany*
erklären in alleiniger Verantwortung, dass das/die Medizinprodukt/e	*declare under our sole responsibility that the medical device/s*
Bezeichnung: MOTOR CONTROL UNIT 2303 MOTOR CONTROL UNIT 2303	*designation:* MOTOR CONTROL UNIT 2303 MOTOR CONTROL UNIT 2303
Typ:	*type:*
2303.001	**2303.011**
allen anwendbaren Anforderungen der Richtlinie 93/42/EWG über Medizinprodukte entspricht.	*meets all applicable requirements of the Medical Device Directive 93/42/EEC.*
Konformitätsbewertungsverfahren Anhang:	*Conformity assessment procedure annex:*
☒ II, ☐ III, ☐ IV,	☐ V, ☐ VI, ☐ VII
Dies ist erkennbar an der nachfolgend aufgeführten CE Kennzeichnung des Produkts und / oder der dem Produkt beigefügten Informationen.	*This is visible by one of the following CE markings on the product and / or the enclosed information.*
☐ CE / CE	☒ CE 0124 / CE 0124 DEKRA Certification GmbH Handwerkstraße 15, 70565 Stuttgart

Gültigkeitsdauer / *Validity:* 2024-05-26

Ort und Datum der Ausstellung: Knittlingen, 2020-05-18

Bereichsleitung Forschung und Entwicklung *Vice-President Research and Development*	: 18.05.2020	J. Rennert	
Abteilungsleitung Zulassung Regulatory Affairs *Senior Director Global Regulatory Affairs*	18.05.2020	A. Völker	
Abteilungsleitung QM & QA *Director QM & QA*	18.05.2020	W. Brunow	
	Datum / *Date*	Name	Unterschrift / *Signature*

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

504,005e

Konformitätserklärung nach Richtlinie 93/42/EWG für Medizinprodukte

Conformity Declaration according to Medical Device Directive 93/42/EEC

Wir	*We*
RICHARD WOLF GMBH Pforzheimer Straße 32 75438 Knittlingen Deutschland	*RICHARD WOLF GMBH* *Pforzheimer Straße 32* *75438 Knittlingen* *Germany*
erklären in alleiniger Verantwortung, dass das/die Medizinprodukt/e	*declare under our sole responsibility that the medical device/s*
Bezeichnung: SAUGPUMPE	*designation:* *SUCTION PUMP*
Typ:	*type:*
2208001	
allen anwendbaren Anforderungen der Richtlinie 93/42/EWG über Medizinprodukte entspricht.	*meets all applicable requirements of the Medical Device Directive 93/42/EEC.*
Konformitätsbewertungsverfahren Anhang:	*Conformity assessment procedure annex:*
☒ II, ☐ III, ☐ IV,	☐ V, ☐ VI, ☐ VII
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☐ CE / CE	☒ CE 0124 / CE 0124 DEKRA Certification GmbH Handwerkstraße 15, 70565 Stuttgart

Gültigkeitsdauer / *Validity:* 2024-05-26

Ort und Datum der Ausstellung: Knittlingen, 2020-05-26

	Datum / *Date*	Name	Unterschrift / *Signature*
Bereichsleitung Forschung und Entwicklung *Vice-President Research and Development*	05.06.2020	J. Rennert	
Abteilungsleitung Zulassung Regulatory Affairs *Senior Director Global Regulatory Affairs*	04.06.2020	A. Völker	
Abteilungsleitung QM & QA *Director QM & QA*	05.06.2020	W. Brunow	

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

Konformitätserklärung nach Richtlinie 93/42/EWG für Medizinprodukte

Conformity Declaration according to Medical Device Directive 93/42/EEC

Wir RICHARD WOLF GMBH Pforzheimer Straße 32 75438 Knittlingen Deutschland	*We* *RICHARD WOLF GMBH* *Pforzheimer Straße 32* *75438 Knittlingen* *Germany*
erklären in alleiniger Verantwortung, dass das/die Medizinprodukt/e	*declare under our sole responsibility that the medical device/s*

Bezeichnung: / *designation:*
* siehe Anlage / * see attached list

Typ: / *type:*

2216001	**4171223**	**4171224**	**4171225**	**8171223**

allen anwendbaren Anforderungen der Richtlinie 93/42/EWG über Medizinprodukte entspricht.

meets all applicable requirements of the Medical Device Directive 93/42/EEC.

Konformitätsbewertungsverfahren Anhang: / *Conformity assessment procedure annex:*

☒ II, ☐ III, ☐ IV, ☐ V, ☐ VI, ☐ VII

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This is visible by one of the following CE markings on the product and / or the enclosed information.

☐ CE / CE

☒ CE 0124 / CE 0124

DEKRA Certification GmbH
Handwerkstraße 15, 70565 Stuttgart

Gültigkeitsdauer / *Validity:* 2024-05-26

Ort und Datum der Ausstellung: Knittlingen, 2020-05-25

Bereichsleitung Forschung und Entwicklung *Vice-President Research and Development*	29.05.2020	J. Rennert	
Abteilungsleitung Zulassung Regulatory Affairs *Senior Director Global Regulatory Affairs*	28.05.2020	A. Völker	
Abteilungsleitung QM & QA *Director QM & QA*	29.05.2020	W. Brunow	
	Datum / *Date*	Name	Unterschrift / *Signature*

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "ENDO-CHIRURGIE" ISO 13485:2003 REPUBLICA MOLDOVA

Typ/ *type/* Modèle/ tipo	Bezeichnung	*designation*	désignation	*denominazione*	designación
2216001	LAP SAUG-SPÜLPUMPE	*LAP SUCT./IRRIG. PUMP*	POMPE D'IRRIG./ASPIR. LAP	*POMPA DI ASPIRAZIONE/IRRIGAZIONE LAP*	BOMBA DE SUC./IRRIG. DE LAP
4171223	SPÜLSCHLAUCH SET MIT ANSTECHDORN L 3M	*IRRIGATION TUBE SET SPIKE L 3M*	SET DE TUBES D'IR.A.BR.D.PER CAGE L 3M	*SET TUBI FLESS. IRRIG. CON PERFOR. L 3M*	SET DE TUBOS DE IRRIG. ESPINA L 3M
4171224	SPÜLSCHLAUCH SET MIT CARE-LOCK L 3M	*IRRIGATION TUBE SET CARE LOCK L 3M*	SET DE TUBES D'IRIG. CARE-LOCK L 3M	*SET DI TUBI CON CARE-LOCK*	SET DE TUBOS DE IRRIG. CARE-LOCK L 3M
4171225	SAUG-SPÜLSCHLAUCH SET L 3M	*SUCTION/IRRIGATION TUBE SET L 3M*	SET DE TUBES D'ASPIR./IRRIG. L 3M	*SET TUBI FLESS. ASPIR./IRRIG. L 3M*	SET DE TUBOS SUC./IRRIG. L 3M
8171223	SPÜLSCHLAUCH SET MIT ANSTECHDORN	*IRRIGATION TUBE SET SPIKE*	SET DE TUBES D'IR.A.BR.D.PER CAGE	*SET TUBI FLESS. IRRIG. CON PERFOR.*	SET DE TUBOS DE IRRIG. ESPINA

Konformitätserklärung nach Richtlinie 93/42/EWG für Medizinprodukte

Conformity Declaration according to Medical Device Directive 93/42/EEC

Wir

RICHARD WOLF GMBH
Pforzheimer Straße 32
75438 Knittlingen
Deutschland

erklären in alleiniger Verantwortung, dass das/die Medizinprodukt/e

We

RICHARD WOLF GMBH
Pforzheimer Straße 32
75438 Knittlingen
Germany

declare under our sole responsibility that the medical device/s

Bezeichnung:
SPÜLPUMPE FÜR HYS/ URO/ LAP
BILANZIERUNGSMODUL
SPÜLPUMPE FÜR HYS/ URO/ LAP

designation:
IRRIGATION PUMP FOR HYS/ URO / LAP
FLUID MONITORING MODUL
IRRIGATION PUMP FOR HYS/ URO/ LAP

Typ: / *type:*

2225001 **2225023** **2225601**

allen anwendbaren Anforderungen der Richtlinie 93/42/EWG über Medizinprodukte entspricht.

meets all applicable requirements of the Medical Device Directive 93/42/EEC.

Konformitätsbewertungsverfahren Anhang: / *Conformity assessment procedure annex:*

☒ II, ☐ III, ☐ IV, ☐ V, ☐ VI, ☐ VII

Dies ist erkennbar an der nachfolgend aufgeführten CE Kennzeichnung des Produkts und / oder der dem Produkt beigefügten Informationen.

This is visible by one of the following CE markings on the product and / or the enclosed information.

☐ CE / CE

☒ CE 0124 / CE 0124

DEKRA Certification GmbH
Handwerkstraße 15, 70565 Stuttgart

Gültigkeitsdauer / *Validity:* 2024-05-26

Ort und Datum der Ausstellung: Knittlingen, 2020-05-15

Bereichsleitung Forschung und Entwicklung *Vice-President Research and Development*	15.05.2020	J. Rennert	
Abteilungsleitung Zulassung Regulatory Affairs *Senior Director Global Regulatory Affairs*	15.05.2020	A. Völker	
Abteilungsleitung QM & QA *Director QM & QA*	18.05.2020	W. Brunow	
	Datum / *Date*	Name	Unterschrift / *Signature*

S.R.L. "ENDO-CHIRURGIE" IDNO 1008600033242 SOCIETATEA CU RĂSPUNDERE LIMITATĂ REPUBLICA MOLDOVA

505,030f

Konformitätserklärung nach Richtlinie 93/42/EWG für Medizinprodukte

Conformity Declaration according to Medical Device Directive 93/42/EEC

Wir	*We*
RICHARD WOLF GMBH Pforzheimer Straße 32 75438 Knittlingen Deutschland	*RICHARD WOLF GMBH* *Pforzheimer Straße 32* *75438 Knittlingen* *Germany*
erklären in alleiniger Verantwortung, dass das/die Medizinprodukt/e	*declare under our sole responsibility that the medical device/s*
Bezeichnung: INSUFFLATIONS-SCHLAUCHSET L 2,7M	*designation:* INSUFFLATION TUBE SET L 2.7M
Typ:	*type:*
4170.501	
allen anwendbaren Anforderungen der Richtlinie 93/42/EWG über Medizinprodukte entspricht.	*meets all applicable requirements of the Medical Device Directive 93/42/EEC.*
Konformitätsbewertungsverfahren Anhang: ☒ II, ☐ III, ☐ IV,	*Conformity assessment procedure annex:* ☐ V, ☐ VI, ☐ VII
Dies ist erkennbar an der nachfolgend aufgeführten CE Kennzeichnung des Produkts und / oder der dem Produkt beigefügten Informationen.	*This is visible by one of the following CE markings on the product and / or the enclosed information.*
☐ CE / CE	☒ CE 0124 / CE 0124 DEKRA Certification GmbH Handwerkstraße 15, 70565 Stuttgart

Gültigkeitsdauer / *Validity:* 2024-05-26

Ort und Datum der Ausstellung: Knittlingen, 2020-06-02

	Datum / *Date*	Name	Unterschrift / *Signature*
Bereichsleitung Forschung und Entwicklung *Vice-President* *Research and Development*	09.06.2020	J. Rennert	
Abteilungsleitung Zulassung Regulatory Affairs *Senior Director Global Regulatory Affairs*	08.06.2020	A. Völker	
Abteilungsleitung QM & QA *Director QM & QA*	10.06.2020	W. Brunow	

S.R.L. "ENDO-CHIRURGIE" SOCIETATEA CU RĂSPUNDERE LIMITATĂ IDNO 1009600033342 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

Lista dispozitivelor medicale solicitate spre notificare					
Nr.	**Numărul de catalog (referință)***	**Denumire generică (denumirea dispozitivului)**	**Denumire comercială (brand)***	**Modelul**	**Cod GMDN***
1	8564.021	Motor de mina	Power Stick M 4-handle	Power Stick M 4	
2	2235001	Insuflator CO2	INSUFFLATOR Highflow 45 BASIC	Highflow 45 BASIC	
3	2235021	Insuflator CO2	INSUFFLATOR Highflow 45 HEAT	Highflow 45 HEAT	
4	2235601	Insuflator CO2	INSUFFLATOR Highflow 45 BASIC	Highflow 45 BASIC	
5	2235621	Insuflator CO2	INSUFFLATOR Highflow 45 HEAT	Highflow 45 HEAT	
6	2235011	Insuflator CO2	INSUFFLATOR Highflow 45 HEAT EVAC + HEAT	Highflow 45 HEAT EVAC + HEAT	
7	2235031	Insuflator CO2	INSUFFLATOR Highflow 45 HEAT EVAC + HEAT	Highflow 45 HEAT EVAC + HEAT	
8	2235611	Insuflator CO2	INSUFFLATOR Highflow 45 HEAT EVAC + HEAT	Highflow 45 HEAT EVAC + HEAT	
9	2235631	Insuflator CO2	INSUFFLATOR Highflow 45 HEAT EVAC + HEAT	Highflow 45 HEAT EVAC + HEAT	
10	2303.001	Motor control unit 2303	Motor control unit 2303	Motor control unit 2303	
11	2303.011	Motor control unit 2303	Motor control unit 2303	Motor control unit 2303	
12	2208001	Suction pump	"PIRANHA" suction pump set	"PIRANHA" suction pump set	
13	2216001	Lap suct./Irrig. Pump	Lap suct./Irrig. Pump	Lap suct./Irrig. Pump	
14	4171223	Irrigation tube set spike L 3M	Irrigation tube set spike L 3M	Irrigation tube set spike L 3M	
15	4171224	Irrigation tube set care lock L 3M	Irrigation tube set care lock L 3M	Irrigation tube set care lock L 3M	
16	4171225	Suction/Irrigation tube set L 3M	Suction/Irrigation tube set L 3M	Suction/Irrigation tube set L 3M	
17	8171223	Irrigation tube set spike	Irrigation tube set spike	Irrigation tube set spike	
18	2225001	Pompa de irigare aspirare	FLUID CONTROL 2225 Suction and irrigation pump	FLUID CONTROL 2225	
19	2225023	Pompa de irigare aspirare	FLUID CONTROL 2225 Suction and irrigation pump	FLUID CONTROL 2225	

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ENDO-CHIRURGIE" S.R.L. IDNO 1009600003942 REPUBLICA MOLDOVA

20	2225601	Pompa de irigare aspirare	FLUID CONTROL 2225 Suction and irrigation pump	FLUID CONTROL 2225	
21	4170.501	Insufflation tube set L 2.7M	Insufflation tube set L 2.7M	Insufflation tube set L 2.7M	

"Endo-Chirurgie" SRL

Data 03.05.2023 Semnătura _____

Dubalari Pavel, jurisconsult

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

ENDO CHIRURGIE

NR. 163/09 din 05/09/2022

ÎMPUTERNICIRE

Subscrisa, **"Endo–Chirurgie" SRL**, cu sediul în Republica Moldova, mun. Chişinău, 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,

.....

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ENDO-CHIRURGIE" IDNO 1009600033242 REPUBLICA MOLDOVA

Digitally signed by Ghereg Victor
Date: 2023.06.11 10:49:33 EEST
Reason: MoldSign Signature
Location: Moldova