

Către: **Agencia Medicamentului și 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. Chișinău, str. Drumul Viilor, nr. 30/2, ap. (of.) 54, **adresa poștală (de corespondență): mun. Chișinău, str. Meșterul 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 și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- **Insuflator CO2 – Richard Wolf**

Se anexează următoarele acte:

- Declarația pe proprie răspundere (RO) – 1 (una) filă.
- Declarația 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 își 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 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	

*La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE*

Către: **AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVE MEDICALE**

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitantul: **"Endo-Chirurgie" SRL**, cu sediul mun. Chișinău, str. Drumul Viilor, nr. 30/2, ap. (of.) 54, **adresa poștală: mun. Chișinău, str. Meșterul Manole, nr. 9**, declară pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale:

- **Insuflator CO2 – Richard Wolf.**

Sunt autentice și corespund realității.

Dubalari Pavel, jurisconsult



**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:
MOTORHANDGRIFF MAX. 6000U/MIN
Typ:

designation:
MOTOR HANDPIECE MAX. 6000RPM
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:

Conformity assessment procedure annex:

☒ II, ☐ III, ☐ IV,

☐ V, ☐ VI, ☐ VII

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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

424,001e

Vordersete

P08F0030 E11

**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:
* siehe Anlage

designation:
* 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:

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☐ V, ☐ VI, ☐ VII

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

Bereichsleitung
Forschung und Entwicklung
Vice-President
Research and Development

: 07.10.2020

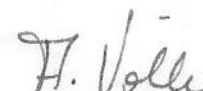
J. Rennert



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



Typ/Type/ Modèle/Tipo	Bezeichnung	Designation	Désignation	Designación
2235001	INSUFFLATO R 45 BASIC FR 45L/MIN	INSUFFLAT OR 45 BASIC FR 45L/MIN	INSUFFLATEU R 45 BASIC DÉBIT 45L/MIN	INSUFLADOR 45 BASIC CAUDAL 45L/MIN
2235021	INSUFFLATO R 45 HEAT FR 45L/MIN	INSUFFLAT OR 45 HEAT FR 45L/MIN	INSUFFLATEU R 45 HEAT DÉBIT 45L/MIN	INSUFLADOR 45 HEAT CAUDAL 45L/MIN
2235601	INSUFFLATO R 45 BASIC FR 45L/MIN	INSUFFLAT OR 45 BASIC FR 45L/MIN	INSUFFLATEU R 45 BASIC DÉBIT 45L/MIN	INSUFLADOR 45 BASIC CAUDAL 45L/MIN
2235621	INSUFFLATO R 45 HEAT FR 45L/MIN	INSUFFLAT OR 45 HEAT FR 45L/MIN	INSUFFLATEU R 45 HEAT DÉBIT 45L/MIN	INSUFLADOR 45 HEAT CAUDAL 45L/MIN



**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:

INSUFFLATOR 45 EVAC FR 45L/MIN
INSUFFLATOR 45 EVAC + HEAT FR 45L/MIN
INSUFFLATOR 45 EVAC FR 45L/MIN
INSUFFLATOR 45 EVAC + HEAT FR 45L/MIN

designation:

INSUFFLATOR 45 EVAC FR 45L/MIN
INSUFFLATOR 45 EVAC + HEAT FR 45L/MIN
INSUFFLATOR 45 EVAC FR 45L/MIN
INSUFFLATOR 45 EVAC + HEAT FR 45L/MIN

Typ:

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:

☒ II, ☐ III, ☐ IV, ☐ V, ☐ VI, ☐ VII

Conformity assessment procedure annex:

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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

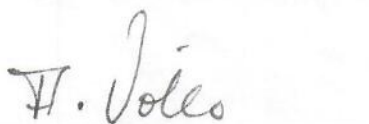
J. Rennert



Abteilungsleitung Zulassung
Regulatory Affairs
Senior Director Global
Regulatory Affairs

: 02.10.2020

A. Völker



Abteilungsleitung
QM & QA
Director
QM & QA



: 08.10.2020

W. Brunow



Datum / Date

Name

Unterschrift / Signature

503,022f

Vorderseite

P08FO030 E11

**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:
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

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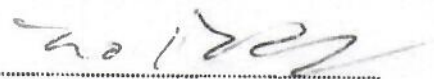
Gültigkeitsdauer / Validity: 2024-05-26

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

Bereichsleitung
Forschung und Entwicklung
Vice-President
Research and Development

: 18.05.2020

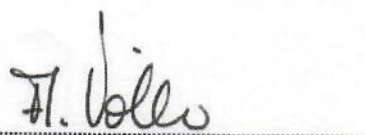
J. Rennert



Abteilungsleitung Zulassung
Regulatory Affairs
Senior Director Global
Regulatory Affairs

18.05.2020

A. Völker



Abteilungsleitung
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QM & QA

18.05.2020

W. Brunow



Datum / Date

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504,005e

Verdarsete

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Richtlinie 93/42/EWG für Medizinprodukte
Conformity Declaration according to
Medical Device Directive 93/42/EEC**

Wir
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Pforzheimer Straße 32
75438 Knittlingen
Deutschland

We
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Pforzheimer Straße 32
75438 Knittlingen
Germany

erklären in alleiniger Verantwortung, dass das/die
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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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Ort und Datum der Ausstellung: Knittlingen, 2020-05-26

Bereichsleitung
Forschung und Entwicklung
Vice-President
Research and Development

: 05.06.2020

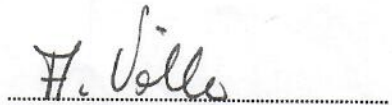
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Abteilungsleitung Zulassung
Regulatory Affairs
Senior Director Global
Regulatory Affairs

: 04.06.2020

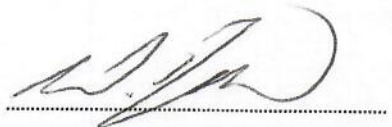
A. Völker



Abteilungsleitung
QM & QA
Director
QM & QA

: 05.06.2020

W. Brunow





Datum / Date

Name

Unterschrift / Signature

**Konformitätserklärung nach
Richtlinie 93/42/EWG für Medizinprodukte
Conformity Declaration according to
Medical Device Directive 93/42/EEC**

Wir
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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:
* siehe Anlage

designation:
* 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:

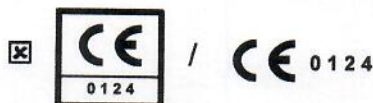
Conformity assessment procedure annex:

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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



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/IRRI- GATION 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

We
RICHARD WOLF GMBH
Pforzheimer Straße 32
75438 Knittlingen
Germany

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Medizinprodukt/e

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:

2225001

type:

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:

☒ II, ☐ III, ☐ IV,

Conformity assessment procedure annex:

☐ V, ☐ VI, ☐ VII

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

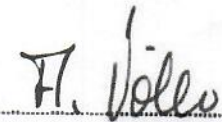
Bereichsleitung
Forschung und Entwicklung
Vice-President
Research and Development

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

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505,030f

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**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

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medical device/s

Bezeichnung:
INSUFFLATIONS-SCHLAUCHSET L 2,7M
Typ:

designation:
INSUFFLATION TUBE SET L 2.7M
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:

Conformity assessment procedure annex:

☒ II, ☐ III, ☐ IV,

☐ V, ☐ VI, ☐ VII

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DEKRA Certification GmbH
Handwerkstraße 15, 70565 Stuttgart

Gültigkeitsdauer / Validity: 2024-05-26

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

Bereichsleitung
Forschung und Entwicklung
Vice-President
Research and Development

: 09.06.2020

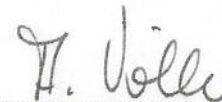
J. Rennert



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





Datum / Date

Name

Unterschrift / Signature

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

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



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 fiberoptic cystourethroscope
- Flexible fiberoptic hysteroscope
- Flexible fiberoptic nasopharyngoscope
- Flexible fiberoptic 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



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

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

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



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



TO WHOM IT MAY CONCERN

spirit of excellence

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.

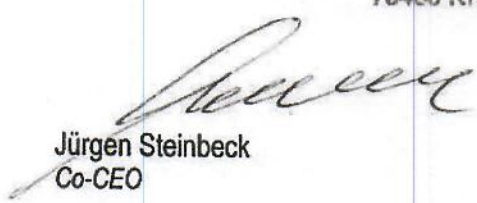
Furthermore, the company is able to organize the commissioning, functional testing as well as warranty and post-warranty service procedure for the related products in cooperation with and on behalf of the Richard Wolf GmbH.

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

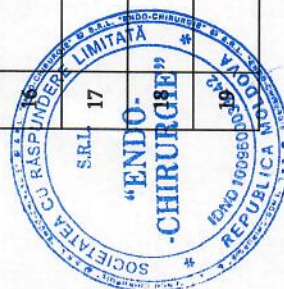
RICHARD WOLF GMBH **RICHARD WOLF**
GmbH
75438 KNITTLINGEN


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	



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



Semnătura

Dubalari Pavel, juriconsult

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 **GHREG Victor**, în calitate de administrator, prin prezenta îl împuternicesc pe domnul **DUBALARI Pavel**, IDNP 2001003326049, angajat în cadrul companiei în calitate de juriconsult, 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 nementionată expres dar necesară îndeplinirii prezentului mandat va avea acordul meu.

Împuternicirea este valabilă pînă la data de 31.12.2023.

Administrator,

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