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. 90/09 din 21.09.2023

Solicitantul, **"Endo–Chirurgie" SRL**, cu sediul social în: mun. Chișinău, 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 și punerea la dispoziție pe piață a:

- **Instrumente chirurgicale pentru intervenţii Endourologice– Richard Wolf**.
- **Instrumente pentru intervenţii chirurgicale Laparoscopice – Richard Wolf**.

Se anexează următoarele acte:

- Declarația pe proprie răspundere (RO) – 1 (una) filă.
- Declarația de conformitate (EN/DE) – 17 (șaptesprezece) file.
- Certificatul de conformitate ISO 13485/EC (EN) – 7 (șapte) file.
- Actul prin care producătorul își desemnează reprezentantul (EN) – 1 (una) filă.
- Copia împuternicirii (RO) – 1 (una) filă.

Data 21.09.2023 Semnătura _____

***Dubalari Pavel**, jurisconsult*

Tabelul de recepţionare 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	

Anexa nr. 2

La Procedurile administrative pentru notificarea

dispozitivelor medicale care dețin marcajul CE

Către: AGENŢIA MEDICAMENTULUI ŞI DISPOZITIVE MEDICALE

DECLARAŢIE 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. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale:

- Instrumente chirurgicale pentru intervenţii Endourologice– Richard Wolf.
- Instrumente pentru intervenţii chirurgicale Laparoscopice – Richard Wolf.

Sunt autentice şi corespund realităţii.

***Dubalari Pavel**, jurisconsult* *Semnătura* _____

Data 21.09.2023

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:*
INNENSCHAFT FÜR RESEKTOSKOP 22CH	INTERNAL SHEATH RESECTOSCOPE 22FR
INNENSCHAFT FÜR RESEKTOSKOP 24CH	INTERNAL SHEATH RESECTOSCOPE 24FR
AUßENSCHAFT FÜR RESEKTOSKOP 24CH	OUTER SHEATH RESECTOSCOPE 24FR
AUßENSCHAFT FÜR RESEKTOSKOP 26CH	OUTER SHEATH RESECTOSCOPE 26FR
Typ:	*type:*
8675322 8675324 8675424 8675426	

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, 2020-06-02

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*

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, 21.02.2022

	Datum / *Date*:	Unterschrift / *Signature*:
Bereichsleitung Forschung und Entwicklung / *Vice-President Research and Development*:	21.02.2022	Jens Rennert
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

Produktliste / *Product List*

Materialnummer/Typ *Material number/Type*	Produkt- und Handelsname *Product and trade name*	Risikoklasse *Risk class*
8676342	VERBINDUNGSTEIL FÜR RESEKTOSKOP 24CH *CONNECTING PART RESECTOSCOPE 24FR*	I
8676343	VERBINDUNGSTEIL FÜR RESEKTOSKOP 26CH *CONNECTING PART RESECTOSCOPE 26FR*	I
8654.3642	VERBINDUNGSTEIL FÜR RESEKTOSKOP 22,5CH *CONNECTING PART RESECTOSCOPE 22.5FR*	I
8654.3742	VERBINDUNGSTEIL FÜR RESEKTOSKOP 24CH *CONNECTING PART RESECTOSCOPE 24FR*	I
8654.3842	VERBINDUNGSTEIL FÜR RESEKTOSKOP 26CH *CONNECTING PART RESECTOSCOPE 26FR*	I

Basis UDI-DI / *Basic UDI-DI*: 405520711032019-0028403AE

Verwendungszweck

Die Produkte dienen zum Anschluss des Resektoskop-Innenschafts am Arbeitselement und ermöglichen somit das Einführen von Hilfsinstrumenten.

Intended use

The products are used for connecting the resectoscope sheath to the working element thus allowing the insertion of auxiliary instruments.

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:*
SCHAFT FÜR URETHROTOM 20,5CH AUßENSCHAFT FÜR URETHROTOM 20,5CH	SHEATH FOR URETHROTOME 20.5FR OUTER SHEATH FOR URETHROTOME 20.5FR
Typ:	*type:*
8667.011	**8667.161**

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, 2020-12-08

Bereichsleitung
Forschung und Entwicklung
Vice President
Research and Development 11.12.2020 J. Rennert

Bereichsleitung
Qualität und Regulatorik
Vice President Global
Quality Assurance and
Regulatory Affairs 11.12.2020 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	*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: OBTURATOR FÜR URETHROTOM 20,5CH	*designation:* OBTURATOR FOR URETHROTOME 20.5FR
Typ:	*type:*
8667.111	

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, 2021-02-16

Bereichsleitung
Forschung und Entwicklung
Vice President
Research and Development

17.02.2021 J. Rennert

Bereichsleitung
Qualität und Regulatorik
Vice President Global
Quality Assurance and
Regulatory Affairs

17.02.2021 W. Brunow

Datum / *Date* Name Unterschrift / *Signature*

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, 21.02.2022

	Datum / *Date*:	Unterschrift / *Signature*:
Bereichsleitung Forschung und Entwicklung / *Vice-President Research and Development*:	21.02.2022	Jens Rennert
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

Produktliste / *Product List*

Materialnummer/Typ *Material number/Type*	Produkt- und Handelsname *Product and trade name*	Risikoklasse *Risk class*
8667.911	ARBEITSELEMENT URETHROTOM PASSIV 0/12° *WORKING ELEMENT URETHRO PASSIVE 0/12°*	I
8670.911	ARBEITSELEMENT URETHROTOM PASSIV 0° *WORKING ELEMENT URETHRO PASSIVE 0°*	I
8693.914	ARBEITSELEMENT URETHROTOM PASSIV 0° *WORKING ELEMENT URETHRO PASSIVE 0°*	I

Basis UDI-DI / *Basic UDI-DI*: 405520727052019-0018414P9

Verwendungszweck

Die Produkte dienen zum Aufnehmen und Fixieren von Optiken und Strikturskalpellen, sowie zum kontrollierten Einbringen von Strikturskalpellen in Schäfte.

Intended use

The products serve to accomodate and secure telescopes and stricture scalpels and to introduce stricture scalpels in sheaths in a controlled manner.

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:*
SCHAFT FÜR NEPHROSKOP 20,8CH	SHEATH FOR NEPHROSCOPE 20.8FR
AMPLATZSCHAFT FÜR NEPHROSKOP 24,3CH	AMPLATZ SHEATH FOR NEPHROSCOPE 24.3FR
NEPHROSKOP 12° 20,8CH NL 224MM	NEPHROSCOPE 12° 20.8FR WL 224MM
SPÜLANSATZ FÜR NEPHROSKOP	IRRIGATION ADAPTOR FOR NEPHROSCOPE
Typ:	*type:*
8964.021 8964.041	**8964.401 8964.711**

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, 2020-05-28

Bereichsleitung Forschung und Entwicklung *Vice-President* *Research and Development*	: 20.07.2020	J. Rennert	
Abteilungsleitung Zulassung Regulatory Affairs *Senior Director Global Regulatory Affairs*	: 24.07.2020	A. Völker	
Abteilungsleitung QM & QA *Director* *QM & QA*	: 21.07.2020	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	*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:*
SCHAFT FÜR NEPHROSKOP 24CH	SHEATH FOR NEPHROSCOPE 24FR
NEPHROSKOP 20° 24CH NL 224MM	NEPHROSCOPE 20° 24FR WL 224MM
NEPHROSKOP 20° 24CH NL 224MM	NEPHROSCOPE 20° 24FR WL 224MM
Typ:	*type:*
8965.041	**8965.401** **8965.411**

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, 2020-05-27

Bereichsleitung Forschung und Entwicklung *Vice-President Research and Development*	: 20.07.2020	J. Rennert	
Abteilungsleitung Zulassung Regulatory Affairs *Senior Director Global Regulatory Affairs*	: 17.07.2020	A. Völker	
Abteilungsleitung QM & QA *Director QM & QA*	: 21.07.2020	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	*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: STARRE GREIFZANGE 10,5CH NL 340MM STARRE GREIFZANGE 10,5CH NL 365MM	*designation:* RIGID GRASP. FORCEPS 10.5FR WL 340MM RIGID GRASP. FORCEPS 10.5FR WL 365MM
Typ:	*type:*
8964.601	**8964.671**
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, 2021-02-23

Bereichsleitung
Forschung und Entwicklung
Vice President
Research and Development

24.02.2021 — J. Rennert

Bereichsleitung
Qualität und Regulatorik
Vice President Global
Quality Assurance and
Regulatory Affairs

02.03.2021 — W. Brunow

Datum / *Date* — Name — Unterschrift / *Signature*

EC DECLARATION OF CONFORMITY
DECLARATION CE DE CONFORMITE
EG-KONFORMITÄTSERKLÄRUNG

Nous, We, Wir,

E.M.S. Electro Medical Systems S.A.,
Chemin de la Vuarpillière 31,
1260 Nyon, Switzerland

déclarons sous notre seule responsabilité que les références du produit :

declare under our sole responsibility that the references of the product :

erklären in alleiniger Verantwortung, daß die Referenzen des Produkts:

Swiss LithoClast 2 (R.WOLF) and Accessories

de satisfont aux dispositions applicables des directives relatives aux dispositifs médicaux 93/42/CEE & 2007/47/CEE, Annexe II (Système complet d'assurance de qualité), hors point (4),

are conforming to the relevant provisions of the Medical Device Directives 93/42/EEC & 2007/47/EEC, Annex II (Full quality assurance system), excluding section (4),

den einschlägigen Bestimmungen der richtlinien 93/42/EWG & 2007/47/EWG Medizinprodukte, Anhang II (Vollständiges Qualitätssicherungssystem), ausser Nummer (4), entsprechen,

sous le numéro de certificat CE :

Under the EC Certificate No. :
50081-16-09

EG Zertifikat-Nr. :

Date de la dernière recertification :

Date of last recertification :
2020-06-15

Datum der letzten Rezertifizierung:

Nom, adresse et numéro d'identification de l'organisme notifié:

Name, address and identification number of Notified Body:
DEKRA Certification GmbH
Handwerkstrasse 15,
70565 Stuttgart, Germany CE 0124

Name, Adresse und Kennnummer der Benannten Stelle:

À l'exception des références de **classe I**, qui satisfont aux dispositions applicables des directives relatives aux dispositifs médicaux 93/42/CEE & 2007/47/CEE, annexe VII (auto-déclaration).

Exception made to the **class I** references (if applicable), which are conforming to the relevant provisions of the Medical Device Directives 93/42/EEC & 2007/47/EEC, annex VII (self-declaration). CE

Ausnahme zu den Referenzen der **Klasse I**, die den einschlägigen Bestimmungen der Medizinprodukterichtlinien 93/42/EWG & 2007/47/EWG, Anhang VII (Selbsterklärung) entsprechen.

La documentation technique est disponible auprès d'E.M.S. Electro Medical Systems S.A.

Technical documentation is kept available by E.M.S. Electro Medical Systems S.A.

Die technische Dokumentation wird durch E.M.S. Electro Medical Systems S.A. gehalten.

Lieu, date

Place, date
Nyon, 2020-06-25

Valid until : 2024-05-26

Ort, Datum

Fonction, nom et signature

Function, name and signature

Funktion, Name und Unterschrift

Product Manager — Jérôme Blondeau .....

Head of Quality — Timothée Deblock .....

E.M.S. Electro Medical Systems S.A.
Chemin de la Vuarpillière 31 , 1260 Nyon , SWITZERLAND . Tel. (022) 99 44 700 . Fax (022) 99 44 701

References of all classes except class I, are compliant with Annex II (Full Quality Assurance System), excluding section (4):

CE 0124

References	R. WOLF References	SET / DEV	Product name	Class 93/42	Rules	CE market release date
FT-189W	2292001	DEV	Swiss LithoClast 2 (R. WOLF)	IIb	9 part 2	2007-11-28
EL-044	8742.004	ACC	LithoClast probe Ø 2,0 x 425 mm (6,0 Ch.)	IIa	5 & 7	N/A
EL-045	8742.002	ACC	LithoClast probe Ø 1,0 x 605 mm (3,0 Ch.)	IIa	5 & 7	N/A
EL-046	8742.001	ACC	LithoClast Probe Ø 0.8 X 605 mm (2,4 Ch.)	IIa	5 & 7	N/A
EL-058	8742.003	ACC	LithoClast Probe Ø 1.6 X 605 mm (4,8 Ch.)	IIa	5 & 7	N/A
EL-079	8742.011	ACC	Probe Ø 0.8 x 558 mm	IIa	5 & 7	N/A
EL-080	8742.012	ACC	LithoClast Probe Ø 0.8 X 668 mm (2,4 Ch.)	IIa	5 & 7	N/A
EL-081	8742.013	ACC	LithoClast Probe Ø 1.6 X 453 mm (4,8 Ch.)	IIa	5 & 7	N/A
EL-092	8742.005	ACC	Probe Ø 3.2 x 425 mm (9,6 Ch.)	IIa	5 & 7	N/A
EL-099	8742.021	ACC	Probe Ø 0.8 x 490 mm	IIa	5 & 7	N/A
EL-101	8742.023	ACC	Probe Ø 1.6 x 490 mm	IIa	5 & 7	N/A
EL-175/A	8745310	ACC	Pneumatic handpiece pn3 R. WOLF	IIb	9, part 2	N/A
EL-182/A	8745103	ACC	Handpiece LithoVac lv3 R. WOLF	IIb	9 part 2	N/A
EL-211	8745.194	ACC	Suction tube Ø4,0 x 353 mm (12 Ch.)	IIa	5 & 7	N/A
EL-212	8745.193	ACC	Suction tube Ø3,5x380 mm (10,5 Ch.)	IIa	5 & 7	N/A
EL-213	8745.192	ACC	Suction tube Ø1,6x595 mm (4,8 Ch.)	IIa	5 & 7	N/A
EL-220	8745.012	ACC	LithoClast Probe Ø 1.0 X 570 mm	IIa	5 & 7	N/A
EL-261	8742.043	ACC	Probe Ø 1.6 x 380 mm	IIa	5 & 7	N/A
EL-276	8745.014	ACC	LithoClast Probe Ø 1.0 X 497 mm	IIa	5 & 7	N/A

References of Class I are compliant with Annex VII (self-declaration):

CE

References	R. WOLF References	SET/DEV/ACC	Product name	Class 93/42	Rules	CE market release date
EK-278	2292871	ACC	Electric foot pedal	I	1	N/A

E.M.S. Electro Medical Systems S.A.
Chemin de la Vuarpillière 31 , 1260 Nyon , SWITZERLAND . Tel. (022) 99 44 700 . Fax (022) 99 44 701

Spare Parts :

EMS References	R. WOLF Referens	DESCRIPTION
AD-347	8745.332	Cap for Ø 0.8 - 2.0 mm pneumatic probes
AD-425	8745.331	Cap for Ø 3.2 mm pneumatic probe
BE-028	4745.976	Silicone seal (packing unit: 20x)
BG-075	8175.715	Spare tube for pneumatic handpiece
CD-012	2295.851	Mains Cord Europe
CD-092	2292852	Main power cord Switzerland
CD-093	2292854	Main power cord Hospital Grade
CD-094	2292850	Main Power cord Europe
CE-068	2292880	Temporised fuses T 1.6A
DP-370	2292991	Carton package LithoClast 2 R. WOLF
DP-375	2292992	Medical neutral packing
DP-295	2292.990	Demonstration hard case
EH-085	2295.804	Compressed air tube (1,0 m)
EH-086	2295.805	Compressed air tube (3.0 m)
EH-091	2295.811	Compressed air tube (Dräger)
EH-092	2292810	Compressed air tube (France)
EH-096	8175.711	Compressed air tube for handpiece
EH-101	2292803	Compressed air hose
EL-219	8745.212	Adjustment Interface lv3 - pn3
EL-237	8745.106	Suction set for Lithovac
EQ-062	8742.051	Bag of Silicone Probe Guides
EQ-063	8742.976	O'rings set
EQ-113	2292889	Set of connectors for exhaust
FR-126	2292025	Stone fragment catcher holder

Note: the # symbol indicates that the product is available as a configurable item with various combinations of optional items.

E.M.S. Electro Medical Systems S.A.
Chemin de la Vuarpillière 31 , 1260 Nyon , SWITZERLAND . Tel. (022) 99 44 700 . Fax (022) 99 44 701

Signature Manifest

Document Number: TFD-140/EEC **Revision:** E
Title: Declaration of conformity - Swiss LithoClast 2 (R.Wolf)

All dates and times are in UTC+01:00.

PU_URO_TFD

Author

Name/Signature	Title	Date	Meaning/Reason
Coline Lahaye (CLH)		25 May 2021, 06:30:44 PM	Approved

Update ERP

Name/Signature	Title	Date	Meaning/Reason
Generic user Notificator (NOTIFICATOR)		25 May 2021, 06:30:44 PM	Email Sent
Coline Lahaye (CLH)		25 May 2021, 06:30:44 PM	Email Sent

OMNIA Srl – Via F. Delnevo, 190 sx – 43036 – Fidenza (Parma)

DICHIARAZIONE DI CONFORMITA'
EC – Declaration of Conformity

Omnia Srl dichiara sotto la propria responsabilità che i dispositivi appartenenti alla famiglia
We declare under our responsibility that the medical device belong to

Sistemi di aspirazione per chirurgia ed odontoiatrica - Suction system for dental surgery and dentistry

Sono classificati/are classified:

Prodotto/Product	**Classificazione/Classification**
Sistemi di aspirazione per calcoli -*Stonecatcher* *32.F7085.00 (DT-059)* = RW 2295.510 *32.F7087.00 (DT-097)*	classificati in Classe I sterile secondo la regola 1 dell'Allegato IX alla Direttiva 93/42/CEE (modificata e aggiornata dalla Direttiva 2007/47/CE) *Class I sterile medical device according to rules 1 Directive 93/42/CEE (and subsequent updating with Directive 2007/47/CEE) - Annex IX*

e sono/ and are:

1) descritti nel Fascicolo Tecnico FT04 e sono conformi alle specifiche della Direttiva 93/42/CEE (modificata e aggiornata dalla Direttiva 2007/47/CE) – la documentazione è conservata presso il fabbricante e a disposizione delle Autorità competenti e dell'Ente Notificato / *described in Technical File FT04 and they are in compliance with Directive 93/42/CEE (and subsequent updating with Directive 2007/47/EC) - technical documentation are retained under the premises of the Manufacturer at disposition of the Competent Authorities and Notified Body*
2) certificati secondo Allegato VII e V della Direttiva 93/42/CEE (modificata e aggiornata dalla Direttiva 2007/47/CE) CE 0546 Organismo Notificato CERTIQUALITY Via G.Giardino, 4 – 20123 Milano - certificato n° 12774/2 - *Certified according to Annex VII e V Directive 93/42/CEE (and subsequent updating with Directive 2007/47/EC) - CE 0546 Notified Body CERTIQUALITY- Via G.Giardino, 4 – 20123 Milano - certificate n° 12774/2*
3) conformi alle disposizioni dell'Allegato I della Direttiva 93/42/CEE modificata e aggiornata dalla Direttiva 2007/47/CE - *In compliance with Annex I Directive 93/42/CEE (updated with Directive 2007/47/EC)*

Fidenza, 19.12.2018

Legal Representative Roberto Cerioli

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: * siehe Anlage	*designation:* * see attached list
Typ: * siehe Anlage	*type:* * see attached list
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, 2021-05-21

Bereichsleitung
Forschung und Entwicklung
Vice President
Research and Development

21.05.2021 J. Rennert

Bereichsleitung
Qualität und Regulatorik
Vice President Global
Quality Assurance and
Regulatory Affairs

21.05.2021 W. Brunow

Datum / *Date* Name Unterschrift / *Signature*

Typ/ *type/* Modèle/ tipo	Bezeichnung	*designation*	désignation	designación
2232.852	CO2 VERBINDUNGSSCHLAUCH	CO2 CONNECTING TUBE	CO2 TUBE DE CONNEXION	TUBO DE CONEXION CO2
8170.101	INSUFFLATIONS-SCHLAUCHSET L 2,5M	INSUFFLATION TUBE SET L 2.5M	SET DE TUBES D'INSUFFLATION L 2,5M	SET DE TUBOS DE INSUFLACIÓN L 2,5M
8170.232	INSUFFLATIONS-SCHLAUCHSET L 2,5M	INSUFFLATION TUBE SET L 2.5M	SET DE TUBES D'INSUFFLATION L 2,5M	SET DE TUBOS DE INSUFLACIÓN L 2,5M
8170.801	HOCHDRUCK-VERBINDUNGSSCHLAUCH L 1M	HIGH PRESSURE CONNECTION TUBE L 1M	TUBE DE CONNEXION HAUTE PRESSION L 1M	MANGUERA DE CONEXION PRESION ALTA L 1M
8170.802	HOCHDRUCK-VERBINDUNGSSCHLAUCH L 1M	HIGH PRESSURE CONNECTION TUBE L 1M	TUBE DE CONNEXION HAUTE PRESSION L 1M	MANGUERA DE CONEXION PRESION ALTA L 1M
8170.803	HOCHDRUCK-VERBINDUNGSSCHLAUCH L 1M	HIGH PRESSURE CONNECTION TUBE L 1M	TUBE DE CONNEXION HAUTE PRESSION L 1M	MANGUERA DE CONEXION PRESION ALTA L 1M
8170.865	SPÜLKANÜLE ZUR TEM NL 215MM	IRRIGATION CANNULA FOR TEM WL 215MM	CANULE D'IRRIGATION POUR TEM LU 215MM	CANULA DE IRRIGACION PARA TEM LU 215MM
8170.3111	CO2 VERBINDUNGSSCHLAUCH L 5M	CO2 CONNECTING TUBE L 5M	CO2 TUBE DE CONNEXION L 5M	TUBO DE CONEXION CO2 L 5M

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

DEKRA Certification GmbH * Stuttgart * Handwerkstraße 15

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

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

Annex to the Certificate No. 50593-14-02

Revision status: 0

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

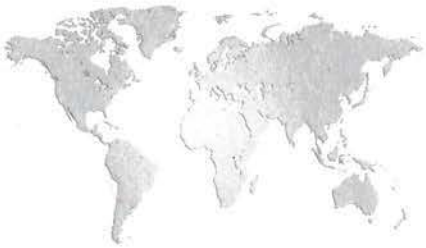
The following locations / companies belong to the certificate above:

	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

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

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 • D-70565

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

34460

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:

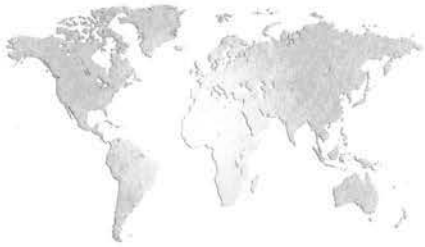
- Electrosurgical system generator
- Endoscopic electrosurgical electrode, bipolar, reusable
- Endoscopic electrosurgical electrode, bipolar, single-use, sterile
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic electrosurgical electrode, monopolar, single-use
- Endoscopic 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

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15 DEKRA DEKRA Certification

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

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex V

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 V 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.: 50593-17-04

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15, D-70565

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

84460

Annex to the EC Certificate No. 50593-17-04

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.

- Endoscope inflation bulb
- Proctoscope, single-use
- Rectoscope, single-use

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565

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

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

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,
.....