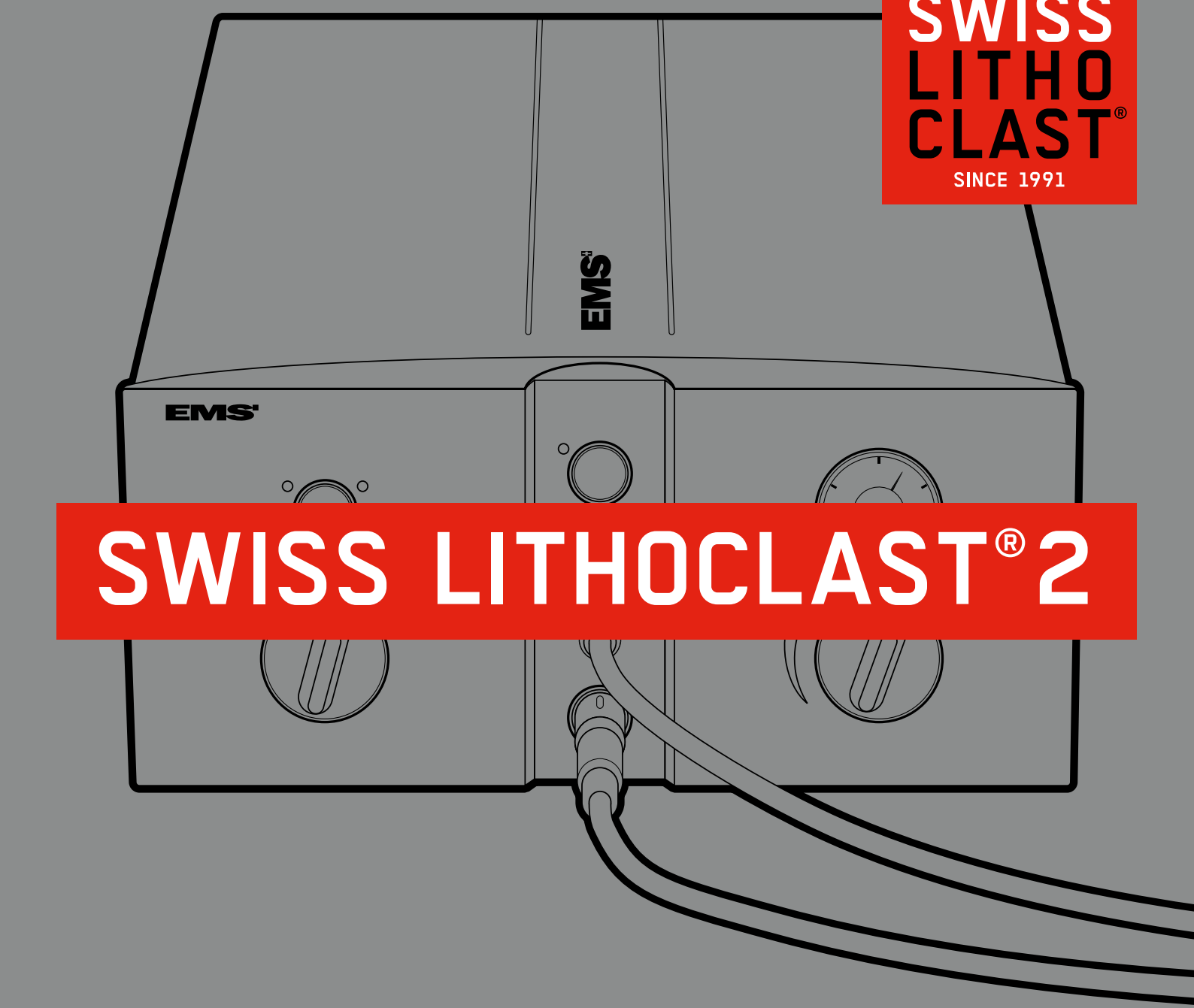
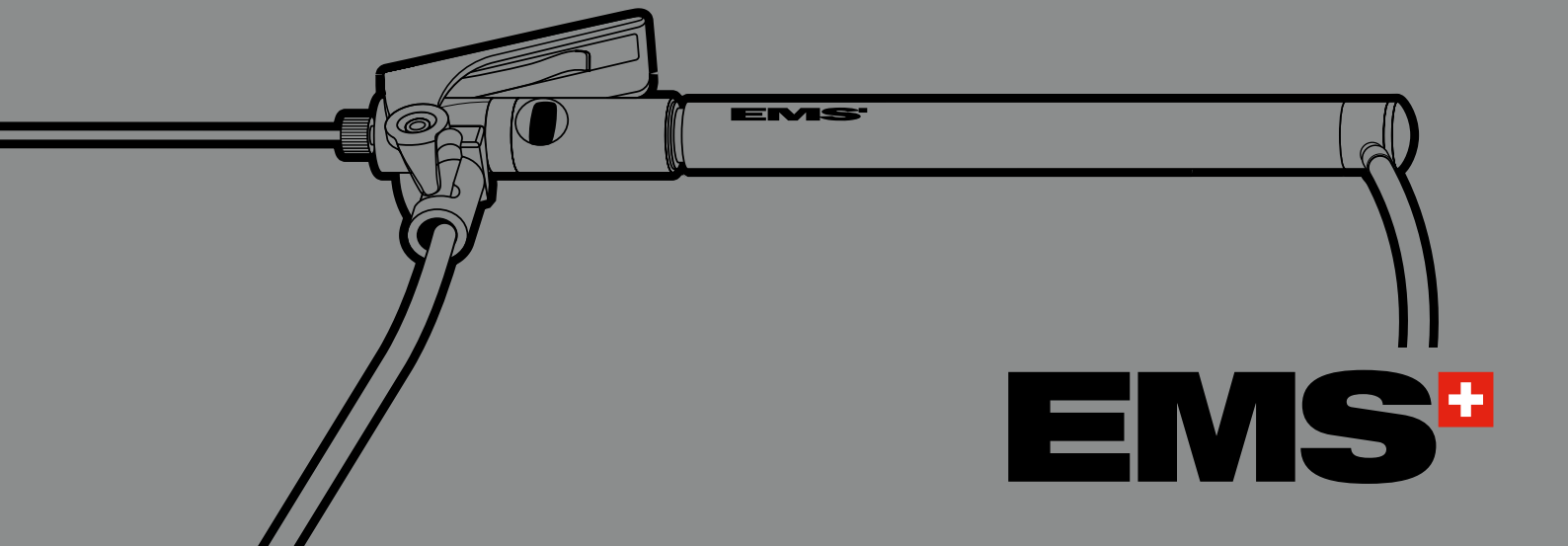
25 YEARS SWISS LITHO CLAST®
SINCE 1991



SWISS LITHOCLAST® 2



EMS

SWISS LITHOCLAST® 2
EVOLUTION

THE GENUINE SWISS LITHOCLAST® 2

THE EVOLUTION IN LITHOCLAST® STONE THERAPY – FROM THE INVENTOR OF THE SWISS LITHOCLAST® METHOD

- → BETTER TREATMENT RESULTS
- → BETTER HANDLING
- → EASIER REPROCESSING

SETTING A NEW STANDARD FOR SAFETY AND EFFECTIVENESS

THE ORIGINAL PNEUMATIC PN3 HANDPIECE – INNOVATIVE FUNCTION AND DESIGN →

THE RESULT OF RESEARCH AND DEVELOPMENT – THE INNOVATIVE HANDPIECE OF THE SWISS LITHOCLAST® 2→

> The Pn3 handpiece is extremely lightweight and ensures optimum operator control with its good ergonomic design.

> The coupling section of the air supply tube rotates and the compressed-air tube is now longer without losing any pulse efficiency. This allows greater freedom of movement for the user in all treatment situations.

> The Pn3 handpiece and compressed-air tube is a sealed system and can be autoclaved or sterilized without additional sealing caps. This means no penetration of liquids and moisture, no blocking of the projectile and no related handpiece failure.

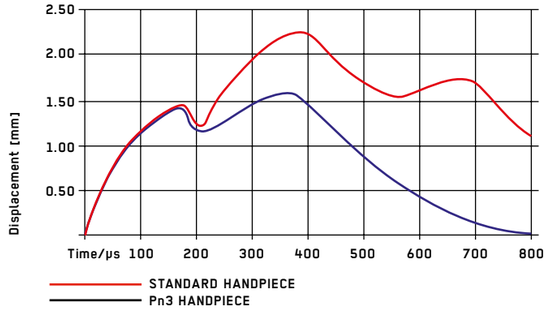
> The quick-connection probe caps provide easy, fast and sterile probe change.

> All components – handpiece and probes – remain extremely durable due to highest material and manufacturing quality.

INNOVATION IN THE HANDS OF THE PHYSICIAN →

→ GREATLY REDUCED PROBE DISPLACEMENT WITH THE Pn3 HANDPIECE IMPROVES FRAGMENTATION CONTROL AND REDUCES PUSH-BACK EFFECT

→ SWISS LITHOCLAST® Pn3 HANDPIECE COMPARED TO STANDARD HANDPIECE – PROBE DISPLACEMENT MEASURED AT A PRESSURE OF 2 BAR



SWISS LITHOCLAST® 2
INNOVATION

PN3→

STATE OF THE ART

Ratio 1:1

FLEXIBLE IMPULSE FREQUENCY, CONTROLLED BY THE PHYSICIAN →

SELECTION OF IMPULSE FREQUENCY IN 12 STEPS, WITH SINGLE IMPULSE SHOTS OR WITH CONTINUOUS IMPULSES ON BOOST FREQUENCY – CONTROLLED BY THE PHYSICIAN THROUGH A DUAL FOOT PEDAL

→ SELECTION OF HIGHER/LOWER IMPULSE FREQUENCY RANGE AND VARIABLE FREQUENCY ADJUSTMENT 1 – 12 Hz

SWISS LITHOCLAST® 2
FLEXIBLE

THE CHALLENGE FOR THE DEVELOPMENT TEAM OF THE SWISS LITHOCLAST® METHOD WAS THE "PUSH-BACK EFFECT" →

> Loss of mobile stones up the ureter, caused by the lithotripsy impulse, was frustrating. This was often caused by an impulse frequency badly suited to the treatment situation. This problem occurs, if the physician cannot control or adapt the impulse frequency quickly and easily.

THE SWISS LITHOCLAST® 2 FIGHTS THE PUSH-BACK EFFECT BY MEANS OF THREE ESSENTIAL INNOVATIONS →

> The impulse frequency can be adjusted in single Hertz increments – by means of the dual foot pedal, the physician can intraoperatively select between single impulse, low impulse frequency and boost frequency.

> The probe displacement has been greatly reduced – this reduces forward momentum on the stone at impact.

> The newly developed Swiss LithoVac® suction system – suction lithotripsy in the ureter – enables continuous irrigation ureteroscopy and controls the push-back effect on its own.

→ SELECTION OF SINGLE IMPULSES, OR PRESET IMPULSE FREQUENCY OR BOOST FREQUENCY VIA A DUAL FOOT PEDAL

EVERYTHING IS UNDER CONTROL

SWISS LITHOCLAST® 2
CONTROLLED

FLEXIBILITY LINKED TO CONTROL →

NEWLY DEVELOPED SWISS LITHOVAC® SUCTION SYSTEM FOR CONTINUOUS IRRIGATION URETEROSCOPY HELPS TO CONTROL THE PUSH-BACK EFFECT →

CLINICAL PROOF FOR THE EFFECTIVENESS OF THE SWISS LITHOVAC® SUCTION SYSTEM →

> Stenzl, Seibold et al. – Pneumatic lithotripsy with an optional suction device (LithoVac®) for treatment of ureteric stones – Japanese Journal of Endourology, vol. 9, No.1, 1996

> Haupt, Pannek et al. – The LithoVac®: New suction device for the Swiss LithoClast®, Journal of Endourology, vol. 9, No. 5, 1995

FIRST-SHOT SOLUTION →

SAFE AND SUCCESSFUL LITHOTRIPSY WITH VERY SHORT TREATMENTS, INDEPENDENT OF STONE COMPOSITION

→ SUCCESSFUL TREATMENT OF ALL TYPES OF URINARY STONES

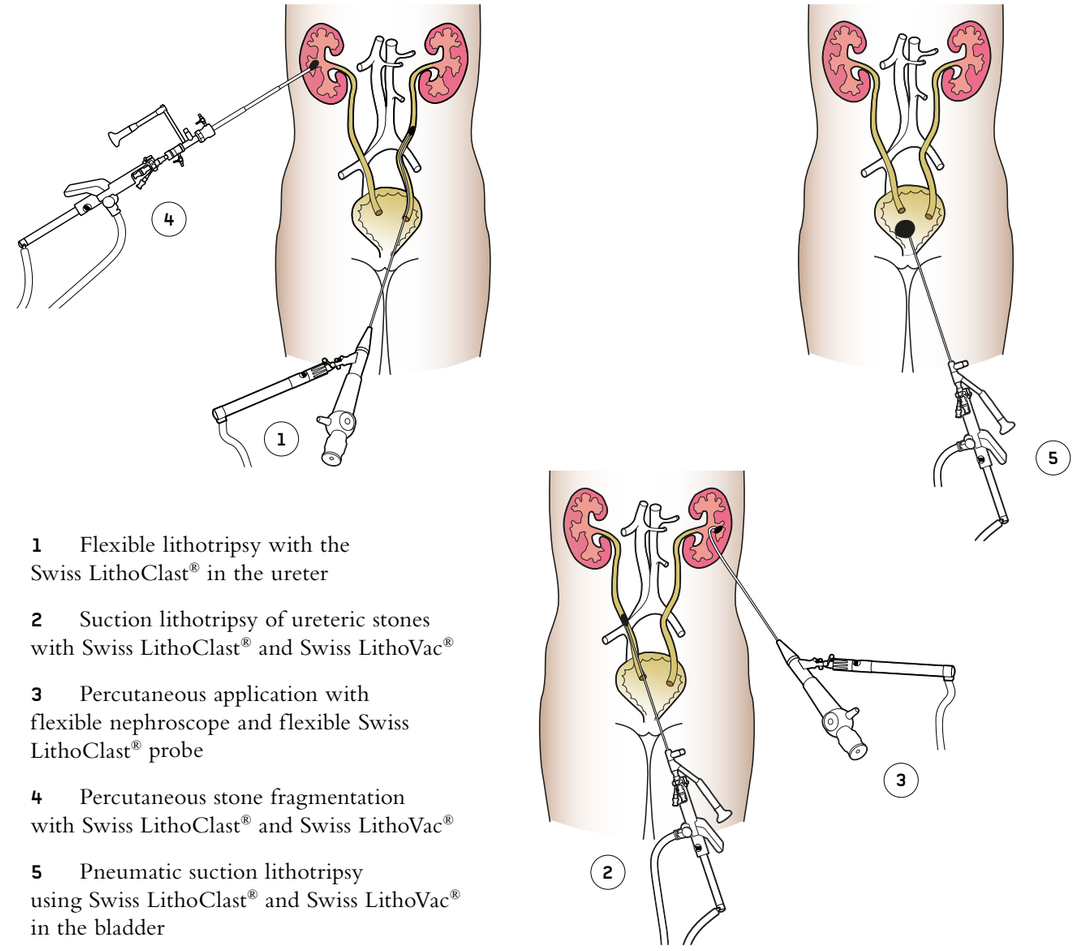
Urinary stones, fragmented
Image scale approx. 4:1

URINARY STONES OF DIFFERENT COMPOSITION – FRAGMENTED WITH THE SWISS LITHOCLAST® METHOD →

> The Swiss LithoClast® transmits energy from the probe onto the stone – thermal tissue damage is excluded.

> The urothelium remains intact even after being hit repeatedly with impulses at the highest energy setting of the Swiss LithoClast® 2.

LARGE, MEDIUM, SMALL →



1 Flexible lithotripsy with the Swiss LithoClast® in the ureter

2 Suction lithotripsy of ureteric stones with Swiss LithoClast® and Swiss LithoVac®

3 Percutaneous application with flexible nephroscope and flexible Swiss LithoClast® probe

4 Percutaneous stone fragmentation with Swiss LithoClast® and Swiss LithoVac®

5 Pneumatic suction lithotripsy using Swiss LithoClast® and Swiss LithoVac® in the bladder

THE SWISS LITHOCLAST® METHOD TREATS ALL STONES IN ALL LOCATIONS

SWISS LITHOCLAST® 2, SWISS LITHOCLAST® ENDOSCOPES, SWISS LITHOVAC® SUCTION → THE GENUINE SWISS LITHOCLAST® METHOD

> Safe, effective and cold: these are the main features of the genuine Swiss LithoClast® Method – developed by EMS – since it's market introduction in 1990.

> The Swiss LithoClast® generates energy without heat development – thermal damage in the urinary tract is eliminated for maximum tissue safety.

> No electrical energy is used for generating the acoustic waves – the highest safety for the patient and physician is guaranteed.

> The outstanding effectiveness of the Swiss LithoClast® results in short treatment duration, independent of the stone composition, with the flexibility of use in the entire urinary tract. And, last but not least, it is the quality of all components, as well as their ease of use and maintenance which made this a unique success.

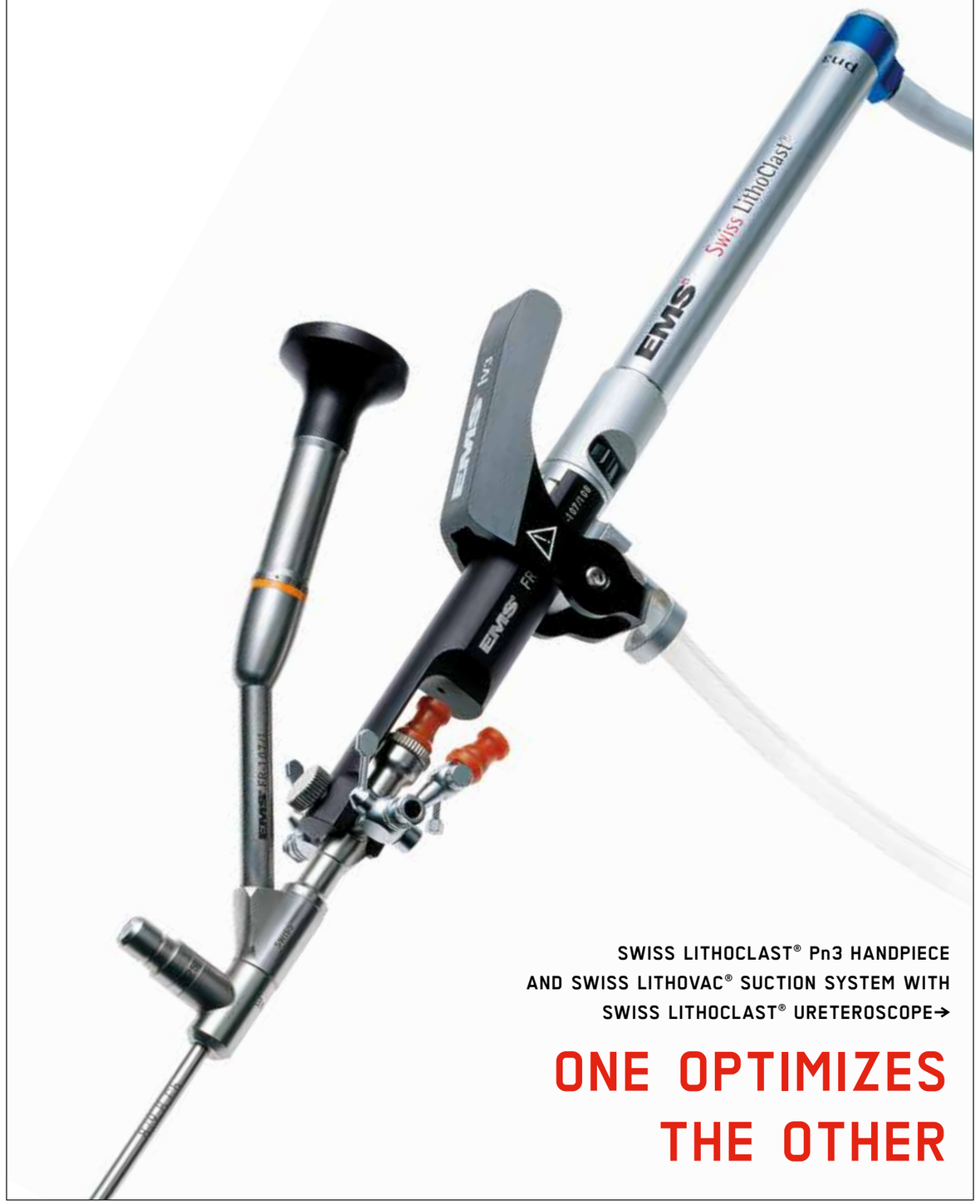
THE ROAD TO SUCCESS →

> The newly developed Swiss LithoVac® suction system is user friendly and easy to clean and to sterilize.

> The new generation of Swiss LithoClast® endoscopes has an impressive and outstanding optical system – ureteroscopy with 50000 Pixel image resolution in small-diameter scopes represents a new dimension in endoscopic image quality.

> The Swiss LithoClast® endoscopes enhance stone therapy – simple, safe handling, no kinking of lithotripsy and suction probes thanks to special guidance adapters.

THE GENUINE SWISS LITHOCLAST® METHOD – FOR MORE THAN A DECADE THE MODERN TERM FOR ENDOSCOPIC LITHOTRIPSY, SETTING THE BENCHMARK FOR SAFE AND EFFECTIVE STONE THERAPY



SWISS LITHOCLAST® Pn3 HANDPIECE
AND SWISS LITHOVAC® SUCTION SYSTEM WITH
SWISS LITHOCLAST® URETEROSCOPE→

ONE OPTIMIZES THE OTHER

SWISS LITHOCLAST®2
SYSTEM

DEVICES, OPTIONS, ACCESSORIES → COVERING ALL NEEDS FOR A SUCCESSFUL STONE THERAPY

SWISS LITHOCLAST®2

Swiss LithoClast®2 basic unit — FT-158#
100–240 VAC, 40 VA, 50/60 Hz
incl. dual foot pedal, compressed-air connection,
pneumatic Pn3 handpiece,
Swiss LithoClast® probes 0.8/1/1.6/2 mm

STONE CATCHER

Stone catcher holder — FR-126
Stone catcher sterile (box of ten) — DT-059

> Stone catcher: collection of stone fragments

SWISS LITHOVAC®

Swiss LithoVac® set lv3 — FR-127#
Suction probe Ø 1.6 mm, 595 mm length — EL-213
Suction probe Ø 3.5 mm, 380 mm length — EL-212
Suction probe Ø 4 mm, 353 mm length — EL-211

SWISS LITHOCLAST® PROBES

Probe Ø 2 mm, 425 mm length — EL-044
Probe Ø 1.6 mm, 605 mm length — EL-058
Probe Ø 1 mm, 605 mm length — EL-045
Probe Ø 0.8 mm, 605 mm length — EL-046
Probe Ø 3.2 mm, 425 mm length — EL-092
Handpiece probe cap for 3.2-mm probe — AD-425
Probe Ø 1.6 mm, 453 mm length
for suction probe EL-212 — EL-081
Probe Ø 0.8 mm, 668 mm length
for suction probe EL-213 — EL-080
Flexible probe Ø 0.89 mm, 940 mm length
for flexible ureterorenoscopes — EL-254B
Flexible probe Ø 0.89 mm, 600 mm length
for flexible nephroscopes — EL-304B

ADAPTERS FOR ENDOSCOPES

For EMS Lithovision ureterorenoscope
FR-167 and FR-168 — FR-172

For Richard Wolf ureterorenoscope
FR-107, FR-108 and FR-132 — FR-114

For Olympus OES Pro Serie
ureterorenoscope WA29042A with
irrigation attachment A0396 — FR-211

STERILIZATION TRAY

Sterilization tray 700 x 120 x 75 mm,
autoclavable — FR-107, FR-108, FR-112

STERILIZATION TRAY

Sterilization tray 500 x 200 x 60 mm,
autoclavable — FR-082, FR-166

MILLIONS

OF STONES CANNOT BE WRONG

THE SWISS LITHOCLAST® PRINCIPLE IS TODAY'S MOST COMMONLY USED ENDOSCOPIC STONE TREATMENT METHOD – ITS PROVEN SAFETY AND ITS SUCCESS RATES MAKE IT ALSO THE MOST EFFICIENT AND COST-EFFECTIVE MODALITY

25 YEARS SWISS LITHOCLAST®
SINCE 1991

BEST RESULTS

FOUR HUNDRED AND TWELVE (412) PUBLISHED STUDIES ON THE SWISS LITHOCLAST® AND PNEUMATIC LITHOTRIPSY PROVIDE AMPLE CLINICAL EVIDENCE ON EFFICIENCY AND SAFETY OF THE SWISS LITHOCLAST® METHOD

HIGH STONE-FREE RATES

> Up to 95% for ureteral stones using pneumatic lithotripsy

> Up to 90% for PNL procedures using combination lithotripsy

HIGH TISSUE SAFETY

> The highest tissue safety of all endoscopic lithotripters

FAST FRAGMENTATION AND CLEARANCE TIME

> Combination mode with the Swiss LithoClast® Master clears stones twice as fast as ultrasound-alone lithotripters

> Pneumatic lithotripters with the Swiss LithoClast® fragments stones on average faster than Holmium laser

BEST COSTS

A FASTER STONE CLEARANCE WITH THE SWISS LITHOCLAST® RESULTS IN A SHORTER OPERATING TIME FOR COST-EFFECTIVE OR MANAGEMENT

> Save 28 minutes compared to laser lithotripsy[1]

> OR time costs 62 $ per minute[2]

> Save on average 1,736 $ per PNL compared to laser lithotripsy

HISTORY & FUTURE

[1] Malik, Rizvi et. al, 2007: Comparison of HO-YAG laser and Swiss LithoClast® in percutaneous nephrolithotomy

[2] A. Macario, Stanford University USA, 2010: What does one minute of operating room time cost?

WWW.EMS-UROLOGY.COM

EMS
ELECTRO MEDICAL SYSTEMS SA
Chemin de la Vuarpillière 31
CH-1260 Nyon

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Fax +41 22 99 44 701
welcome@ems-ch.com

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

E.M.S. Electro Medical Systems S.A.

Chemin de la Vuarpillière 31, 1260 Nyon, Switzerland

Certified location:

Chemin de la Vuarpillière 31, 1260 Nyon, Switzerland
E.M.S. Electro Medical Systems S.A., Rte. de Champ-Colin 2, 1260 Nyon, Switzerland
E.M.S. Electro Medical Systems S.A., Rte. de Champ-Colin 18, 1260 Nyon, Switzerland
E.M.S. Foncine S.A.S., Rte. de Pontarlier 32, 39460 Foncine-le-Haut, France

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. 50081-Z7-00, the decision dated 2020-06-15 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2020-06-15 to 2024-05-26

Registration No.: 50081-16-09

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-06-15
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. 50081-16-09

Valid from 2020-06-15 to 2024-05-26

Revision status of the annex: 0 dated 2020-06-15

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.

IntraCorporal Lithotripters systems
- Stone Catcher

Class II a:

IntraCorporal Lithotripters systems
- Swiss LITHOPUMP
- Probes (pneumatic, ultrasound and combined)
- Probes Sets (pneumatic, ultrasound and combined)

Piezo-ceramic systems for dentistry - Piezon
- PIEZON product group
- PIEZON Surgery product group
- PIEZON Handpieces, PIEZON instruments

Air abrasion / air polisher devices for dental prophylaxis
- AIRFLOW product group
- PERIOFLOW nozzles
- AIRFLOW, PERIOFLOW Handpieces

Air abrasion / air polisher devices for dental prophylaxis with Piezo-ceramic systems for dentistry
- AIRFLOW / PIEZON product group

Surgical HO_YAG laser systems
- SmartFibers product group

Class II b:

IntraCorporal Lithotripters systems
- LITHOCLAST product group
- LITHOCLAST handpieces (pneumatic, ultrasound and combined)
- Handpiece Sets (pneumatic, ultrasound and combined)

ExtraCorporal shock wave therapy systems
- DOLORCLAST product group
- DOLORCLAST Handpieces, DOLORCLAST applicators

Surgical HO_YAG laser-system
- Swiss LASERCLAST product group

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer

DEKRA Certification GmbH, Stuttgart, 2020-06-15
Notified Body ID-number: 0124

Signature Manifest

Document Number: CER-0002 **Revision:** D

Title: EC certificate for the Quality Assurance System according the Directive 93/42/EEC, Annex II excluding section (4)

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

CER-0002 EC certificate

Author and reviewers

Name/Signature	Title	Date	Meaning/Reason
Timothée Deblock (TDE)		29 Jun 2020, 03:46:27 PM	Approved

DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

E.M.S. Electro Medical Systems S.A.
Mr. Timothée Deblock
Ch. de la Vuarpillière 31
1260 Nyon
Switzerland

DEKRA Certification GmbH
Handwerkstraße 15
D-70565 Stuttgart

Headquarters
Phone +49.711.7861-2566
Fax +49.711.7861-2615

Date 2024-05-02

Subject: Notified Body Confirmation Letter

Our reference: 50081-CoL-00, Rev.0

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Dear Mr. Deblock

This letter confirms that, DEKRA Certification GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0124 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

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

SRN Number: CH-MF-000026136

The devices covered by the formal application and the written agreement mentioned above are identified in the Table provided in the Annex. This table identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive MDD.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment

procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Stephanie Donner
2024-05-02

Enclosures:

Confirmation Letter Annex

Annex to Notified Body Confirmation Letter 50954-CoL-00, Rev.0

Devices covered by this letter and for which the Notified body DEKRA Certification GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
07613353001KQ **LithoClast TRILOGY**	Class IIb excluding Class IIb implantable non-WET	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353008L6 **LithoClast Master**	Class IIb excluding Class IIb implantable non-WET	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353013KX **LithoClast 2**	Class IIb excluding Class IIb implantable non-WET	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353040L2 **LITHO Handpieces**	Class IIb excluding Class IIb implantable non-WET	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353011KT **LITHO Probes**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:**

			DEKRA (0124)
07613353048LJ **LASER Fibers**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353039LH **Stone Catcher**	Class I devices placed on the market in sterile condition	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353051L7 **Handpieces Suction Tubes**	Class I devices placed on the market in sterile condition	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353002KS **AIRFLOW Prophylaxis Master and AIRFLOW One**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353030KX **PIEZON 250**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353028LC **PIEZON Kits**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
07613353033L5 **AIRFLOW Handy 3.0**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353021KW **PIEZON Handpieces**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353016L5 **PERIOFLOW Handpieces**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353035L9 **AIRFLOW Handpieces**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353037LD **PIEZON Instruments**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
07613353036LB **PERIOFLOW Nozzles**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353034L7 **Radial Shock Wave**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353031KZ **DolorClast Master**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353026L8 **DolorClast Smart 20**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353046LE **DOLOR Handpieces**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
07613353037LD **PIEZON Instruments**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353049LL **Probes Suction Tubes**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353019LB **LithoPump**	Class IIa	N/A	**Certificate number:** 50081-16-09 **Notified Body:** DEKRA (0124)

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 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:

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.

Nom et adresse du Mandataire:

Name and address of the Authorized Representative:

Name und anschrift des Bevollmächtigter:

E.M.S. Electro Medical Systems FRANCE SARL
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Lieu, date

Place, date
Nyon, 2021-05-25

Valid until : 2024-05-26

Ort, Datum

Fonction, nom et signature	**Function, name and signature**	**Funktion, Name und Unterschrift**
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References of all classes except class I, are compliant with Annex II (Full Quality Assurance System), excluding section (4):

CE 0124

References	SET/DEV/ACC	Product name	Class 93/42	Rules	CE market release date
FT-158#	SET	Swiss LithoClast® 2	IIb	9, part 2	2007-04-10
FT-158DA	SET	Swiss LithoClast® 2	IIb	9, part 2	2009-12-17
FR-127#	SET	LithoVac lv3 Set	IIb	9, part 2	N/A
FR-127	SET	LithoVac lv3 Set	IIb	9, part 2	N/A
EL-304B	SET	3 x LithoClast FlexProbe®	IIa	5 & 7	N/A
EL-254B	SET	3 x LithoClast FlexProbe®	IIa	5 & 7	N/A
EL-254	ACC	FlexProbe	IIa	5 & 7	N/A
FR-089#	ACC	Pneumatic handpiece pn3 set	IIb	9, part 2	N/A
FR-089	ACC	Pneumatic handpiece pn3	IIb	9, part 2	N/A
EL-535	ACC	LithoClast Probe Ø1.3 x 410 mm	IIa	5 & 7	N/A
EL-535#	ACC	Probe LithoClast Ø1.3 X 410 mm	IIa	5 & 7	N/A
EL-552#	ACC	LithoClast Probe Ø0.8 x 410mm (2,4 Ch .)	IIa	5 & 7	N/A
EL-293#	ACC	Probe Ø1 x 636 mm	IIa	5 & 7	N/A
EL-293	ACC	Probe Ø1 x 636 mm	IIa	5 & 7	N/A
EL-276#	ACC	Probe Ø1 x 497 mm	IIa	5 & 7	N/A
EL-276	ACC	LithoClast Probe Ø1.0 x 497mm	IIa	5 & 7	N/A
EL-264#	ACC	Probe Ø1 x 482 mm	IIa	5 & 7	N/A
EL-264	ACC	Probe Ø1 x 482 mm	IIa	5 & 7	N/A
EL-261#	ACC	Probe Ø1.6 x 380 mm	IIa	5 & 7	N/A
EL-261	ACC	Probe Ø1.6 x 380 mm	IIa	5 & 7	N/A
EL-255#	ACC	Probe Ø1.3 x 570 mm	IIa	5 & 7	N/A
EL-255	ACC	Probe Ø1.3 x 570 mm	IIa	5 & 7	N/A
EL-237	ACC	Suction set for Lithovac	IIb	9, part 2	N/A
EL-220#	ACC	Probe Ø1.0 x 570 mm	IIa	5 & 7	N/A
EL-220	ACC	LithoClast Probe Ø1.0 x 570 mm	IIa	5 & 7	N/A
EL-213#	ACC	Suction tube Ø1,6 x 595 mm (4,8 Ch.)	IIa	5 & 7	N/A
EL-213	ACC	Suction tube Ø1,6 x 595 mm (4,8 Ch.)	IIa	5 & 7	N/A
EL-212	ACC	Suction tube Ø3,5 x 380 mm (10,5 Ch.)	IIa	5 & 7	N/A
EL-212#	ACC	Suction tube Ø3,5 x 380 mm (10,5 Ch.)	IIa	5 & 7	N/A
EL-211#	ACC	Suction tube Ø4,0 x 353 mm (12 Ch.)	IIa	5 & 7	N/A
EL-211	ACC	Suction tube Ø4,0 x 353 mm (12 Ch.)	IIa	5 & 7	N/A
EL-182	ACC	LithoVac lv3	IIa	5 & 7	N/A
EL-175	ACC	Pneumatic handpiece pn3	IIa	5 & 7	N/A
EL-101#	ACC	Probe Ø1.6 x 490 mm	IIa	5 & 7	N/A
EL-101	ACC	Probe Ø1.6 x 490 mm	IIa	5 & 7	N/A
EL-099#	ACC	Probe Ø0.8 x 490 mm	IIa	5 & 7	N/A
EL-099	ACC	Probe Ø0.8 x 490 mm	IIa	5 & 7	N/A
EL-092#	ACC	Probe Ø 3.2 x 425 mm (9,6 Ch.) for LithoClast or LithoBreaker	IIa	5 & 7	N/A
EL-092	ACC	Probe Ø3.2 x 425 mm (9,6 Ch.)	IIa	5 & 7	N/A
EL-081#	ACC	Probe Ø 1,6 x 453 mm (4,8 Ch.)	IIa	5 & 7	N/A

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		for LithoClast or LithoBreaker			
EL-081	ACC	LithoClast Probe Ø 1.6 X 453 mm (4,8 Ch.)	IIa	5 & 7	N/A
EL-081/A	ACC	LithoBreaker Probe Ø 0,8 x 668 mm (2,4 Ch.)	IIa	5 & 7	N/A
EL-080#	ACC	Probe Ø 0,8 x 668 mm (2,4 Ch.) for LithoClast or LithoBreaker	IIa	5 & 7	N/A
EL-080	ACC	LithoClast Probe Ø 0.8 X 668 mm (2,4 Ch.)	IIa	5 & 7	N/A
EL-080/A	ACC	LithoBreaker Probe Ø 0,8 x 668 mm (2,4 Ch.)	IIa	5 & 7	N/A
EL-079#	ACC	Probe Ø0.8 x 558 mm	IIa	5 & 7	N/A
EL-079	ACC	Probe Ø0.8 x 558 mm	IIa	5 & 7	N/A
EL-058#	ACC	Probe Ø 1,6 x 605 mm (4,8 Ch.) for LithoClast or LithoBreaker	IIa	5 & 7	N/A
EL-058	ACC	LithoClast Probe Ø 1.6 X 605 mm (4,8 Ch.)	IIa	5 & 7	N/A
EL-058/A	ACC	LithoBreaker probre Ø 1,6 x 605 mm (4,8 Ch.)	IIa	5 & 7	N/A
EL-046#	ACC	Probe Ø 0.8 x 605 mm (2,4 Ch.) for LithoClast or LithoBreaker	IIa	5 & 7	N/A
EL-046	ACC	LithoClast Probe Ø 0.8 X 605 mm (2,4 Ch.)	IIa	5 & 7	N/A
EL-046/A	ACC	LithoBreaker probe Ø 0,8 x 605 mm (2,4 Ch.)	IIa	5 & 7	N/A
EL-045#	ACC	Probe Ø 1 x 605 mm (3,0 Ch.) for LithoClast or LithoBreaker	IIa	5 & 7	N/A
EL-045	ACC	LithoClast Probe Ø 1 X 605 mm (3,0 Ch.)	IIa	5 & 7	N/A
EL-045/A	ACC	LithoBreaker probe Ø 1 x 605 mm (3,0 Ch.)	IIa	5 & 7	N/A
EL-044#	ACC	Probe Ø 2 x 425 mm (6,0 Ch.) for LithoClast or LithoBreaker	IIa	5 & 7	N/A
EL-044	ACC	LithoClast Probe Ø 2 X 425 mm (6,0 Ch.)	IIa	5 & 7	N/A
EL-044/A	ACC	LithoBreaker probe Ø 2,0 x 425 mm (6,0 Ch.)	IIa	5 & 7	N/A
EL-298B	ACC	3 x LithoClast FlexProbe®	IIa	5 & 7	N/A
EL-299B	ACC	3 x LithoClast FlexProbe®	IIa	5 & 7	N/A

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

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