

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



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


Ruth Delbeck-Bayer



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

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

**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. :**
50081-16-08**EG Zertifikat-Nr. :****Date de la dernière recertification :****Date of last recertification :**
2017-07-14**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  0124**Name, Adresse und Kenn-
nummer 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). 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, 2019-08-19**Ort, Datum**

Valid until : 2020-07-13

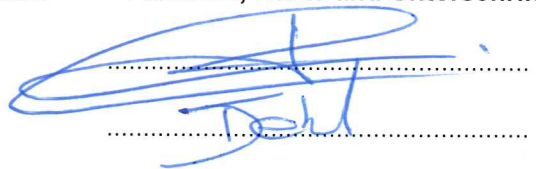
Fonction, nom et signature**Function, name and signature****Funktion, Name und Unterschrift**

Project/Product Manager

Jean-Christophe Prandi

Head of Quality

Timothée Deblock



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



References	SET/DEV/ACC	Product name	Class 93/42	Rules	CE market release date
FT-158#	SET	Swiss LithoClast® 2	Ilb	9, part 2	2007-04-10
FT-158DA	SET	Swiss LithoClast® 2	Ilb	9, part 2	2009-12-17
FR-127#	SET	LithoVac Iv3 Set	Ilb	9, part 2	N/A
EL-304B	SET	3 x LithoClast FlexProbe®	Ila	5 & 7	N/A
EL-254B	SET	3 x LithoClast FlexProbe®	Ila	5 & 7	N/A
FR-089#	ACC	Pneumatic handpiece pn3 set	Ilb	9, part 2	N/A
EL-448	ACC	Pneumatic Probe Ø0.8 x 1000mm	Ila	5 & 7	N/A
EL-535	ACC	LithoClast Probe Ø1.3 x 410 mm	Ila	5 & 7	N/A
EL-535#	ACC	Probe LithoClast Ø1.3 X 410 mm	Ila	5 & 7	N/A
EL-552#	ACC	LithoClast Probe Ø0.8 x 410mm (2,4 Ch.)	Ila	5 & 7	N/A
EL-293#	ACC	Probe Ø1 x 636 mm	Ila	5 & 7	N/A
EL-293	ACC	Probe Ø1 x 636 mm	Ila	5 & 7	N/A
EL-276#	ACC	Probe Ø1 x 497 mm	Ila	5 & 7	N/A
EL-276	ACC	LithoClast Probe Ø1.0 x 497mm	Ila	5 & 7	N/A
EL-264#	ACC	Probe Ø1 x 482 mm	Ila	5 & 7	N/A
EL-264	ACC	Probe Ø1 x 482 mm	Ila	5 & 7	N/A
EL-261#	ACC	Probe Ø1.6 x 380 mm	Ila	5 & 7	N/A
EL-261	ACC	Probe Ø1.6 x 380 mm	Ila	5 & 7	N/A
EL-255#	ACC	Probe Ø1.3 x 570 mm	Ila	5 & 7	N/A
EL-255	ACC	Probe Ø1.3 x 570 mm	Ila	5 & 7	N/A
EL-237	ACC	Suction set for Lithovac	Ilb	9, part 2	N/A
EL-220#	ACC	Probe Ø1.0 x 570 mm	Ila	5 & 7	N/A
EL-220	ACC	LithoClast Probe Ø1.0 x 570 mm	Ila	5 & 7	N/A
EL-213#	ACC	Suction tube Ø1,6 x 595 mm (4,8 Ch.)	Ila	5 & 7	N/A
EL-213	ACC	Suction tube Ø1,6 x 595 mm (4,8 Ch.)	Ila	5 & 7	N/A
EL-212	ACC	Suction tube Ø3,5 x 380 mm (10,5 Ch.)	Ila	5 & 7	N/A
EL-212#	ACC	Suction tube Ø3,5 x 380 mm (10,5 Ch.)	Ila	5 & 7	N/A
EL-211#	ACC	Suction tube Ø4,0 x 353 mm (12 Ch.)	Ila	5 & 7	N/A
EL-211	ACC	Suction tube Ø4,0 x 353 mm (12 Ch.)	Ila	5 & 7	N/A
EL-182	ACC	LithoVac Iv3	Ila	5 & 7	N/A
EL-175	ACC	Pneumatic handpiece pn3	Ila	5 & 7	N/A
EL-101#	ACC	Probe Ø1.6 x 490 mm	Ila	5 & 7	N/A
EL-101	ACC	Probe Ø1.6 x 490 mm	Ila	5 & 7	N/A
EL-099#	ACC	Probe Ø0.8 x 490 mm	Ila	5 & 7	N/A
EL-099	ACC	Probe Ø0.8 x 490 mm	Ila	5 & 7	N/A
EL-092#	ACC	Probe Ø 3.2 x 425 mm (9,6 Ch.) for LithoClast or LithoBreaker	Ila	5 & 7	N/A
EL-092	ACC	Probe Ø3.2 x 425 mm (9,6 Ch.)	Ila	5 & 7	N/A
EL-081#	ACC	Probe Ø 1,6 x 453 mm (4,8 Ch.) for LithoClast or LithoBreaker	Ila	5 & 7	N/A
EL-081	ACC	LithoClast Probe Ø 1.6 X 453 mm (4,8 Ch.)	Ila	5 & 7	N/A
EL-080#	ACC	Probe Ø 0,8 x 668 mm (2,4 Ch.) for LithoClast or LithoBreaker	Ila	5 & 7	N/A
EL-080	ACC	LithoClast Probe Ø 0.8 X 668 mm (2,4 Ch.)	Ila	5 & 7	N/A
EL-079#	ACC	Probe Ø0.8 x 558 mm	Ila	5 & 7	N/A
EL-079	ACC	Probe Ø0.8 x 558 mm	Ila	5 & 7	N/A
EL-058#	ACC	Probe Ø 1,6 x 605 mm (4,8 Ch.) for LithoClast or LithoBreaker	Ila	5 & 7	N/A
EL-058	ACC	LithoClast Probe Ø 1.6 X 605 mm (4,8 Ch.)	Ila	5 & 7	N/A
EL-046#	ACC	Probe Ø 0.8 x 605 mm (2,4 Ch.) for LithoClast or LithoBreaker	Ila	5 & 7	N/A

EL-046	ACC	LithoClast Probe Ø 0.8 X 605 mm (2,4 Ch.)	Ila	5 & 7	N/A
EL-045#	ACC	Probe Ø 1 x 605 mm (3,0 Ch.) for LithoClast or LithoBreaker	Ila	5 & 7	N/A
EL-045	ACC	LithoClast Probe Ø 1 X 605 mm (3,0 Ch.)	Ila	5 & 7	N/A
EL-044#	ACC	Probe Ø 2 x 425 mm (6,0 Ch.) for LithoClast or LithoBreaker	Ila	5 & 7	N/A
EL-044	ACC	LithoClast Probe Ø 2 X 425 mm (6,0 Ch.)	Ila	5 & 7	N/A

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



References	SET/DEV/ACC	Product name	Class 93/42	Rules	CE market release date
FR-125	ACC	Stone Catcher ACL	I	1	N/A
FR-211	ACC	Adapter Olympus URS OES4000 / LithoClast pn3 Handpiece	I	1	N/A
EK-216A	ACC	Electric Footpedal	I	1	N/A

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