

**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 Master, LCM21 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 Kenn-
nummer 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
32, Route de Pontarlier
39460 Foncine-Le-Haut – France**Lieu, date****Place, date****Ort, Datum**

Nyon, 2021-05-25

Valid until : 2024-05-26

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

Marketing Manager, Urology

Jérôme Blondeau

Head of Quality

Timothée Deblock

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-207#	SET	Swiss LithoClast LCM21	IIb	9 part 2	2010-07-29
FT-128#	SET	Swiss LithoClast Master	IIb	9, part 2	2007-04-10
FR-159#	SET	Upgrade kit Vario Ultrasound handpiece	IIb	9, part 2	N/A
FR-159	SET	Upgrade kit Vario Ultrasound handpiece	IIb	9, part 2	N/A
FR-127#	SET	Lithovac Iv3 Set	IIb	9, part 2	N/A
FR-127	SET	LithoVac Iv3 Set	IIb	9, part 2	N/A
FR-089	ACC	Pneumatic handpiece kit pn3	IIb	9, part 2	N/A
FR-089#	ACC	Pneumatic handpiece pn3 set	IIb	9, part 2	N/A
EN-055#	ACC	Vario Ultrasound handpiece	IIb	9, part 2	N/A
EN-055	ACC	Vario Ultrasound handpiece	IIb	9, part 2	N/A
EL-237	ACC	Suction set for Lithovac	IIb	9, part 2	N/A
EL-182	ACC	LithoVac Iv3	IIb	9, part 2	N/A
FR-142#	ACC	Vario Ultrasound handpiece Set	IIb	9, part 2	N/A
FR-142	ACC	Vario Ultrasound handpiece kit	IIb	9, part 2	N/A
FR-106	ACC	Ultrasound Probe Ø 3.8 X 330 mm	IIa	5 & 7	N/A
FR-105	ACC	Ultrasound Probe Ø 3.3 X 330 mm	IIa	5 & 7	N/A
FR-103	ACC	Ultrasound Probe Ø 1.9 X 360 mm	IIa	5 & 7	N/A
FR-102	ACC	Ultrasound Probe Ø 1.5 X 573 mm	IIa	5 & 7	N/A
FR-084	ACC	Ultrasound Probe Ø 3.3 X 403 mm	IIa	5 & 7	N/A
FR-083	ACC	Ultrasound Probe Ø 3.8 X 403 mm	IIa	5 & 7	N/A
EL-552#	ACC	LithoClast Probe Ø0.8 x 410mm (2,4 Ch.)	IIa	5 & 7	N/A
EL-535#	ACC	Probe LithoClast Ø 1.3 X 410 mm	IIa	5 & 7	N/A
EL-535	ACC	LithoClast Probe Ø 1.3 x 410 mm	IIa	5 & 7	N/A
EL-304B	SET	3 x LithoClast FlexProbe®	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 Ø 1 X 497 mm	IIa	5 & 7	N/A
EL-276	ACC	LithoClast Probe Ø 1.0 X 497 mm	IIa	5 & 7	N/A
EL-264#	ACC	Probe Ø 1 x 482 mm	IIa	5 & 7	N/A
EL-264	ACC	Probe Ø 1 x 482 mm	IIa	5 & 7	N/A
EL-261#	ACC	Probe Ø 1.6 X 380 mm	IIa	5 & 7	N/A
EL-261	ACC	Probe Ø 1.6 x 380 mm	IIa	5 & 7	N/A
EL-255#	ACC	Probe Ø 1.3 x 570 mm	IIa	5 & 7	N/A
EL-255	ACC	Probe Ø 1.3 x 570 mm	IIa	5 & 7	N/A

EL-254	ACC	Flex Probe	Ila	5 6 7	N/A
EL-254B	SET	3 x LithoClast FlexProbe®	Ila	5 & 7	N/A
EL-220#	ACC	Probe Ø 1.0 X 570 mm	Ila	5 & 7	N/A
EL-220	ACC	LithoClast Probe Ø 1.0 X 570 mm	Ila	5 & 7	N/A
EL-213#	ACC	Suction tube Ø1,6x595 mm (4,8 Ch.)	Ila	5 & 7	N/A
EL-213	ACC	Suction tube Ø1,6x595 mm (4,8 Ch.)	Ila	5 & 7	N/A
EL-212#	ACC	Suction tube Ø3,5x380 mm (10,5 Ch.)	Ila	5 & 7	N/A
EL-212	ACC	Suction tube Ø3,5x380 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-175	ACC	Pneumatic handpiece pn3	Ila	5 & 7	N/A
EL-101#	ACC	Probe Ø 1.6 x 490 mm	Ila	5 & 7	N/A
EL-101	ACC	Probe Ø 1.6 x 490 mm	Ila	5 & 7	N/A
EL-099#	ACC	Probe Ø 0.8 x 490 mm	Ila	5 & 7	N/A
EL-099	ACC	Probe Ø 0.8 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 Ø 3.2 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-081/A	ACC	LithoBreaker 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-080/A	ACC	LithoBreaker Probe Ø 0,8 x 668 mm (2,4 Ch.)	Ila	5 & 7	N/A
EL-079#	ACC	Probe Ø 0.8 x 558 mm	Ila	5 & 7	N/A
EL-079	ACC	Probe Ø 0.8 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-058/A	ACC	LithoBreaker 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-046/A	ACC	LithoBreaker 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 1,0 x 605 mm (3,0 Ch.)	Ila	5 & 7	N/A
EL-045/A	ACC	LithoBreaker 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 2,0 x 425 mm (6,0 Ch.)	Ila	5 & 7	N/A
EL-044/A	ACC	LithoBreaker probe Ø 2,0 x 425 mm (6,0 Ch.)	Ila	5 & 7	N/A
EL-298B	ACC	3 x LithoClast FlexProbe®	Ila	5 & 7	N/A
EL-299B	ACC	3 x LithoClast FlexProbe®	Ila	5 & 7	N/A

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