

**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 TRILOGY 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**<sub>0124</sub>**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**  
Nyon, 2021-05-25**Ort, Datum**

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-232#	SET	SWISS LITHOCLAST TRILOGY	I Ib	9, part 2	2018-12-17
FT-232	DEV	SWISS LITHOCLAST TRILOGY control unit	I Ib	9, part 2	2018-12-17
FR-278#	ACC	SWISS LITHOCLAST TRILOGY Handpiece kit	I Ib	9, part 2	2018-12-17
FR-278	ACC	SWISS LITHOCLAST TRILOGY Handpiece kit	I Ib	9, part 2	2018-12-17
EN-075#	ACC	SWISS LITHOCLAST TRILOGY Handpiece	I Ib	9, part 2	2018-12-17
EN-075	ACC	SWISS LITHOCLAST TRILOGY Handpiece	I Ib	9, part 2	2018-12-17
FR-254	ACC	SWISS LITHOCLAST TRILOGY DISPOSABLE PROBE Ø 1.1mm x 625mm	I Ia	5,7	2018-12-17
FR-253	ACC	SWISS LITHOCLAST TRILOGY DISPOSABLE PROBE Ø 1.1mm x 520mm	I Ia	5,7	2018-12-17
FR-252	ACC	SWISS LITHOCLAST TRILOGY DISPOSABLE PROBE Ø 1.1mm x 425mm	I Ia	5,7	2018-12-17
FR-250	ACC	SWISS LITHOCLAST TRILOGY DISPOSABLE PROBE Ø 1.5mm x 440mm	I Ia	5,7	2018-12-17
FR-249	ACC	SWISS LITHOCLAST TRILOGY DISPOSABLE PROBE Ø 1.9mm x 341mm	I Ia	5,7	2018-12-17
FR-248	ACC	SWISS LITHOCLAST TRILOGY DISPOSABLE PROBE Ø 3.4mm x 445mm	I Ia	5,7	2018-12-17
FR-247	ACC	SWISS LITHOCLAST TRILOGY DISPOSABLE PROBE Ø 3.4 mm x 340 mm	I Ia	5,7	2018-12-17
FR-246	ACC	SWISS LITHOCLAST TRILOGY DISPOSABLE PROBE Ø 3.9 mm x 440 mm	I Ia	5,7	2018-12-17
FR-245	ACC	SWISS LITHOCLAST TRILOGY DISPOSABLE PROBE Ø 3.9 mm x 350 mm	I Ia	5,7	2018-12-17
DT-483	SET	Stone Catcher for SWISS LITHOCLAST TRILOGY	I Is	1	2018-12-17

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