


**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 DolorClast smart, Swiss DolorClast smart20 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 **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

+33 3 84 51 90 01

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**

Business Unit Manager

Jean-Christophe Prandi

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
EL-157	ACC	Applicator ø6mm	IIb	9, part 2	N/A
EL-158	ACC	Applicator ø15mm	IIb	9, part 2	N/A
EL-272	ACC	Trigger Applicator	IIb	9, part 2	N/A
EL-288	ACC	Applicator ø10mm	IIb	9, part 2	N/A
EL-322	ACC	Applicator Power ø15mm	IIb	9, part 2	N/A
EL-324	ACC	Applicator Power ø10mm	IIb	9, part 2	N/A
EL-325	ACC	Trigger Applicator Power	IIb	9, part 2	N/A
EL-342	ACC	Focus Applicator Power	IIb	9, part 2	N/A
EL-346	ACC	Applicator Power ø36mm	IIb	9, part 2	N/A
FR-115	SET	Applicators set	IIb	9, part 2	N/A
FR-116	SET	Applicators set	IIb	9, part 2	N/A
FR-119	SET	Handpiece Kit DolorClast	IIb	9, part 2	N/A
FR-119#	SET	Handpiece kit Swiss DolorClast	IIb	9, part 2	N/A
FR-119A	SET	Handpiece kit EVO BLUE DolorClast	IIb	9, part 2	N/A
FR-119A-CN	SET	Handpiece kit EVO BLUE DolorClast	IIb	9, part 2	N/A
FR-119B	SET	Handpiece kit Swiss DolorClast	IIb	9, part 2	N/A
FR-140	SET	Handpiece Kit DolorClast Power	IIb	9, part 2	N/A
FR-140#	SET	Handpiece Kit Swiss DolorClast Power	IIb	9, part 2	N/A
FR-140B	SET	Handpiece Kit DolorClast Power	IIb	9, part 2	N/A
FR-213	ACC	Applicator Set EVO Ø10	IIb	9, part 2	N/A
FR-214	ACC	Applicator Set EVO Ø15	IIb	9, part 2	N/A
FR-215	ACC	Applicator Set EVO Ø15 Trigger	IIb	9, part 2	N/A
FR-216	ACC	Applicator Set EVO Ø15 focus	IIb	9, part 2	N/A
FR-217	ACC	Applicator Set EVO Ø36	IIb	9, part 2	N/A
FT-203#	SET	SWISS DOLORCLAST smart	IIb	9, part 2	2010-09-24
FT-226#	SET	SWISS DOLORCLAST smart20	IIb	9, part 2	2013-11-01
EL-508	SET	Handpiece DolorClast EVO	IIb	9, part 2	N/A
EL-317	SET	DolorClast Power Handpiece	IIb	9, part 2	N/A
EL-297	ACC	Handpiece DolorClast	IIb	9, part 2	N/A

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