

**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:**DolorClast Radial Shock Waves & 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:**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). **CE**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, 2020-10-14**Ort, Datum**

Valid until : 2024-05-26

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

Product 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-1003	ACC	Handpiece blue Applicator Ø40	IIb	9, part 2	2020-04-15
EL-1004	ACC	Handpiece blue Applicator Ø25	IIb	9, part 2	2020-04-15
EL-1005	ACC	Handpiece blue Applicator Ø15	IIb	9, part 2	2020-04-15
EL-1006	ACC	Handpiece blue Applicator Ø15 focus	IIb	9, part 2	2020-04-15
EL-1007	ACC	Handpiece blue Applicator Ø15 trigger	IIb	9, part 2	2020-04-15
EL-1008	ACC	Handpiece blue Applicator Ø10	IIb	9, part 2	2020-04-15
EL-1009	ACC	Handpiece blue Applicator Ø5	IIb	9, part 2	2020-04-15
EL-695	ACC	DolorClast RSW blue handpiece	IIb	9, part 2	2020-04-15
FR-301	ACC	DolorClast RSW blue handpiece Kit	IIb	9, part 2	2020-04-15
FR-301#	ACC	DolorClast RSW blue handpiece Kit	IIb	9, part 2	2020-04-15
FR-319	ACC	Handpiece blue Applicator Ø40	IIb	9, part 2	2020-04-15
FR-320	ACC	Handpiece blue Applicator Ø25	IIb	9, part 2	2020-04-15
FR-321	ACC	Handpiece blue Applicator Ø15	IIb	9, part 2	2020-04-15
FR-322	ACC	Handpiece blue Applicator Ø15 focus	IIb	9, part 2	2020-04-15
FR-323	ACC	Handpiece blue Applicator Ø15 trigger	IIb	9, part 2	2020-04-15
FR-324	ACC	Handpiece blue Applicator Ø10	IIb	9, part 2	2020-04-15
FR-325	ACC	Handpiece blue Applicator Ø5	IIb	9, part 2	2020-04-15
FR-334	ACC	Applicator Kit Standard	IIb	9, part 2	2020-04-15
FR-335	ACC	Applicator Kit Advanced	IIb	9, part 2	2020-04-15
FR-346	ACC	Applicator Kit Advanced without Ø40	IIb	9, part 2	2020-04-15
FT-237	DEV	DolorClast Radial Shock Waves	IIb	9, part 2	2020-04-15
FT-237#	SET	DolorClast Radial Shock Waves	IIb	9, part 2	2020-04-15

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
DW-055	ACC	Compact Cart DolorClast	I	1	2020-04-15

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