

**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**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

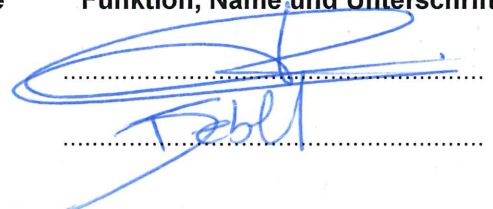
Fonction, nom et signature**Function, name and signature****Funktion, Name und Unterschrift**

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-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 |

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