


**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:**PIEZON® NO PAIN Built in kit (LED) and accessories**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**

Project/Product Manager

Mehdi Sbouaï

Head of Quality

Timothée Deblock

References	SET/DEV/ACC	Product name	Class 93/42	Rules	CE market release date
DS-001A	SET	Instrument A	Ila	5	N/A
DS-003A	SET	Instrument B	Ila	5	N/A
DS-004A	SET	Instrument H	Ila	5	N/A
DS-005A	SET	Instrument D	Ila	5	N/A
DS-010A	SET	File Holder 120°	Ila	5	N/A
DS-011A	SET	Instrument P	Ila	5	N/A
DS-012A	SET	File Holder 90°	Ila	5	N/A
DS-015A	SET	Instrument SP	Ila	5	N/A
DS-016A	SET	Instrument PS	Ila	5	N/A
DS-030A	SET	Instrument PL1	Ila	5	N/A
DS-031A	SET	Instrument PL2	Ila	5	N/A
DS-032A	SET	Instrument PL3	Ila	5	N/A
DS-033A	SET	Instrument PL4	Ila	5	N/A
DS-034A	SET	Instrument PL5	Ila	5	N/A
DS-051A	SET	Instrument SM	Ila	5	N/A
DS-052A	SET	Instrument SD	Ila	5	N/A
DS-057A	SET	Instrument SB	Ila	5	N/A
DS-060A	SET	Instrument SBM	Ila	5	N/A
DS-061A	SET	Instrument SBD	Ila	5	N/A

DS-062A	SET	Instrument PF	Ila	5	N/A
DS-064A	SET	Instrument VE	Ila	5	N/A
DS-065A	SET	Instrument DPL3	Ila	5	N/A
DS-066A	SET	Instrument RT1	Ila	5	N/A
DS-067A	SET	Instrument RT2	Ila	5	N/A
DS-069A	SET	File Holder 180°	Ila	5	N/A
DS-075A	SET	Instrument HPL3	Ila	5	N/A
DT-065A	SET	Instrument PI	Ila	9, part 1	N/A
EN-060#	ACC	PIEZON Handpiece LED	Ila	9, part 1	N/A
EN-061#	ACC	Piezon Handpiece	Ila	9, part 1	N/A
EN-100/A	ACC	PIEZON PS Handpiece	Ila	5	2021-05-25
EN-100#A	ACC	PIEZON PS Handpiece	Ila	5	2021-05-25
FS-213#	SET	System Perio Basic Line 601-4	Ila	9, part 1	N/A
FS-214	SET	System Perio Basic Line 601-5	Ila	9, part 1	N/A
FS-222	SET	System Endo Basic Retro 603-6	Ila	9, part 1	N/A
FS-223#	SET	System Endo Basic Retreatment 603-7	Ila	9, part 1	N/A
FS-279#	SET	Instrument ESI starter kit	Ila	9, part 1	N/A
FS-295#	SET	Instrument PI starter kit	Ila	9, part 1	N/A
FS-304	SET	System Scaling Pro Line 602-5	Ila	9, part 1	N/A
FS-310#	SET	Perio Basic System	Ila	9, part 1	N/A
FS-311#	SET	Perio Plus System	Ila	9, part 1	N/A

FS-312#	SET	Perio Professional System	IIa	9, part 1	N/A
FS-313#	SET	Endo Basic System	IIa	9, part 1	N/A
FS-314#	SET	Endo Plus System	IIa	9, part 1	N/A
FS-343	SET	Perio Basic System	IIa	9, part 1	N/A
FS-367#	SET	PIEZON® NO PAIN Built in kit LED	IIa	9, part 1	2011-03-17
FS-381#	SET	PIEZON® NO PAIN Built in kit	IIa	9, part 1	2011-03-17
FS-437-A	SET	PIEZON NO PAIN BIK LED – A-dec	IIa	9, part 1	2016-07-29
FS-437-B	SET	PIEZON NO PAIN BIK LED – A-dec	IIa	9, part 1	2016-07-29
FS-437-C	SET	PIEZON NO PAIN BIK LED – A-dec	IIa	9, part 1	2016-07-29
FS-438-A	SET	PIEZON NO PAIN BIK – A-dec	IIa	9, part 1	2016-07-29
FS-438-B	SET	PIEZON NO PAIN BIK – A-dec	IIa	9, part 1	2016-07-29
FS-438-C	SET	PIEZON NO PAIN BIK – A-dec	IIa	9, part 1	2016-07-29
FS-453	SET	PIEZON Maintenance Kit	IIa	9, part 1	2017-07-14
FS-1001	ACC	PIEZON PS Handpiece Set	IIa	5	2021-05-25
FV-060	ACC	CombiTorque®	IIa	9, part 1	N/A

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