

**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:**AIRFLOW Prophylaxis Master 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 **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  
+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 Sbouai

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-001A/T	SET	Instrument A x3	Ila	5	2019-08-29
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-011A/T	SET	Instrument P x3	Ila	5	2019-08-29
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-016A/T	SET	Instrument PS x3	Ila	5	2019-08-29
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
DS-083A	ACC	Instrument PSL	Ila	5	2019-03-06
DS-083A/T	SET	Instrument PSL x3	Ila	5	2019-03-06
DS-084A	ACC	Instrument PSR	Ila	5	2019-03-06
DS-084A/T	SET	Instrument PSR x3	Ila	5	2019-03-06
DT-065A	SET	Instrument PI	Ila	9, part 1	N/A
DT-476	SET	40x PERIO-FLOW nozzles marked	Ila	9, part 1	N/A
DT-476A	SET	4x40 PERIO-FLOW nozzles marked	Ila	9, part 1	N/A
DT-476/US	SET	40x PERIO-FLOW nozzles marked	Ila	9, part 1	2020-09-21

DT-476/A/US	SET	4x40 PERIO-FLOW nozzles marked	Ila	9, part 1	2020-09-21
EL-308#	ACC	AIR-FLOW handpiece 120°	Ila	9, part 1	N/A
EL-308/*	ACC	AIR-FLOW handpiece 120°	Ila	9, part 1	N/A
EL-354#	ACC	PERIO-FLOW Handpiece	Ila	9, part 1	N/A
EL-354/*	ACC	PERIO-FLOW Handpiece	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-441	SET	PIEZON Application	Ila	9, part 1	N/A
FS-442	SET	AIRFLOW Application + ClasenUNO	Ila	9, part 1	N/A
FS-443	SET	PERIOFLOW Application with PI instrument	Ila	9, part 1	N/A
FS-444	SET	PERIOFLOW Application for AIRFLOW	Ila	9, part 1	N/A
FS-445	SET	PIEZON ENDO Application	Ila	9, part 1	N/A
FS-447	ACC	AIRFLOW Application	Ila	9, part 1	N/A
FS-455	SET	PIEZON Handpiece Set	Ila	5 & 9 part 1	2018-10-29
FS-456	SET	HYGIENE MASTER Box	Ila	9, part 1	2018-10-29
FS-457	ACC	AIRFLOW Handpiece Set	Ila	5	2018-10-29
FS-459	SET	Instruments PS PSR PSL	Ila	5	2019-03-06



FS-461	SET	Instruments PSR PSL	Ila	5	2019-03-06
FS-462	SET	PS PIEZON Application	Ila	5	2019-03-06
FS-465	ACC	AIRFLOW MAX Handpiece set	Ila	5	2020-09-22
FS-466	SET	PERIOFLOW Application for AIRFLOW	Ila	5	2019-08-29
FS-467	SET	PERIOFLOW Application with PI instrument	Ila	5	2020-09-22
FS-472	SET	AIRFLOW MAX Application + Clasen UNO	Ila	5	2020-09-22
FS-473	SET	AIRFLOW MAX Application	Ila	5	2020-09-22
FS-474	SET	PERIOFLOW Handpiece set	Ila	5	2020-09-22
FS-1001	ACC	PIEZON PS Handpiece Set	Ila	5	2021-05-25
FT-229	SET	AIRFLOW Prophylaxis Master	Ila	9, part 1	2017-03-30
FV-060	ACC	CombiTorque®	Ila	9, part 1	N/A

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