

**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**₀₁₂₄**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, 2020-09-22**Ort, Datum**

Valid until : 2024-05-26

Fonction, nom et signature

Project/Product Manager

Function, name and signature

Ralph Gaillard

Funktion, Name und Unterschrift

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
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-006	SET	Tube of 6 files ISO 15 (White)	Ila	9, part 1	N/A
DT-007	SET	Tube of 6 files ISO 20 (Yellow)	Ila	9, part 1	N/A

DT-008	SET	Tube of 6 files ISO 25 (Red)	Ila	9, part 1	N/A
DT-009	SET	Tube of 6 files ISO 30 (Blue)	Ila	9, part 1	N/A
DT-010	SET	Tube of 6 files ISO 35 (Green)	Ila	9, part 1	N/A
DT-011	SET	Set of Files	Ila	9, part 1	N/A
DT-043	SET	Set of 10 files Retro Berutti	Ila	9, part 1	N/A
DT-060	SET	Set of Files Rétro Berutti	Ila	9, part 1	N/A
DT-061	SET	Set of Files RE2	Ila	9, part 1	N/A
DT-062	SET	Set of Files RT3	Ila	9, part 1	N/A
DT-065A	SET	Instrument PI	Ila	9, part 1	N/A
DT-069A	SET	Set of 6 Instruments ESI 015	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
DT-484	SET	Tube of 6 instruments ESI 015	Ila	9, part 1	N/A
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
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-452	SET	PIEZON PS 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
FT-229	SET	AIRFLOW Prophylaxis Master	Ila	9, part 1	2017-03-30
FV-060	ACC	CombiTorque®	Ila	9, part 1	N/A

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
DV-048/*	ACC	AIR-FLOW CLASSIC Prophylaxis Powder	I	5, part 1	N/A
DV-070/*	ACC	AIR-FLOW PERIO Prophylaxis Powder	I	5, part 1	N/A
DV-071/*	ACC	AIR-FLOW SOFT Prophylaxis Powder	I	5, part 1	N/A
DV-082/*	ACC	AIR-FLOW PLUS Prophylaxis Powder	I	5, part 1	N/A
DV-167/*	ACC	AIRFLOW PLUS	I	5, part 1	2020-09-22
DW-048A	ACC	AIRFLOW Station+	I	1	2017-08-28
DW-048B	ACC	AIRFLOW Station	I	1	2019-08-29
EK-404A	ACC	Boost wireless pedal	I	12	N/A
EK-404B	ACC	Boost wireless pedal	I	12	N/A
EK-410	ACC	Foot switch	I	12	N/A
EK-410A	ACC	Foot switch	I	12	N/A

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