DECLARATION DE CONFORMITE EU
EU DECLARATION OF CONFORMITY
EU-KONFORMITÄTSERKLÄRUNG

Nous,	We,	Wir,

E.M.S. Electro Medical Systems S.A.,
Chemin de la Vuarpillière 31,
1260 Nyon, Switzerland

Numéro d'Enregistrement Unique :	Single Registration Number (SRN):	Eine Einmalige Registrierungsnummer :
	CH-MF-000026136	
déclarons sous notre seule responsabilité que les Dispositifs Médicaux :	declare under our sole responsibility that the Medical Devices:	erklären in alleiniger Verantwortung, dass die Medizinprodukte:

GBT Machine AIRFLOW Prophylaxis Master and accessories

Selon liste de produits (page 4 à 12)	According to product list (page 4 to 12)	Nach Produktliste (Seite 4 bis 12)
Destination :	Intended purpose:	Zweckbestimmung :
	GBT Machine AIRFLOW Prophylaxis Master and accessories are intended to remove biofilm, stains and calculus from oral hard tissues and materials.	
satisfont aux dispositions applicables du règlement 2017/745 relatif aux Dispositifs Médicaux. Procédure d'évaluation de la conformité : Annexe IX	**are conforming to the relevant provisions of the Medical Device Regulation 2017/745. Conformity assessment pathway: Annex IX**	**den einschlägigen Bestimmungen der Medizinprodukteverordnung 2017/745 entsprechen. Konformitätsbewertungsverfahren: Anhang IX**
sous le numéro de certificat CE :	**Under the EC Certificate No. :**	**EG Zertifikat-Nr. :**
	50081-60-00-02	
Date de la dernière recertification :	**Date of last recertification :**	**Datum der letzten Rezertifizierung:**
	28.02.2025	
Nom, adresse et numéro d'identification de l'organisme notifié:	**Name, address and identification number of Notified Body:**	**Name, Adresse und Nummer der Benannten Stelle:**
	DEKRA Certification GmbH Handwerkstrasse 15, 70565 Stuttgart, Germany 0124	
A l'exception des references de classe I, qui satisfont aux dispositions applicables du règlement 2017/745 relatif aux Dispositifs Médicaux, Article 19 (auto-declaration).	**Exception made to the class I references (if applicable), which are conforming to the relevant provisions of the Medical Device Regulation 2017/745, Article 19 (self-declaration).**	**Ausnahme zu den Referenzen der Klasse I, die den einschlagigen Bestimmungen der Medizinprodukteverordnung 2017/745 entsprechen, Artikel 19 (Selbsterklarung) entsprechen.**

E.M.S. Electro Medical Systems S.A.
Chemin de la Vuarpillière 31 , 1260 Nyon , SWITZERLAND . Tel. (022) 99 44 700 . Fax (022) 99 44 701

Nom et adresse du Mandataire: | **Name and address of the Authorized Representative:** | **Name und anschrift des Bevollmächtigter:**

EMS FRANCE SARL
32, Route de Pontarlier
39460 Foncine-Le-Haut – France
+33 3 84 51 90 01
SRN: FR-AR-000011266

We also declare, based on the documentation provided by our suppliers and our own knowledge, that the products listed in **pages 4 to 12**, that are electrical and/or electronic products, are conforming to the relevant provisions of the RoHS Directive 2011/65/EU and amendment 2015/863/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment, meaning that the concentration of the 10 substances mentioned below are not exceeding the limits as defined in the RoHS Directives:

Restricted Substance	Maximum concentration values per homogenous materials
Lead (Pb)	0.1% (w/w)
Cadmium (Cd)	0.01% (w/w)
Hexavalent chromium (CrVI)	0.1% (w/w)
Mercury (Hg)	0.1% (w/w)
Polybrominated biphenyls (PBB)	0.1% (w/w)
Polybrominated diphenyl ether (PBDE)	0.1% (w/w)
Bis(2-ethylhexyl) phthalate (DEHP)	0.1% (w/w)
Butyl benzyl phthalate (BBP)	0.1% (w/w)
Dibutyl phthalate (DBP)	0.1% (w/w)
Diisobutyl phthalate (DIBP)	0.1% (w/w)

The only exception that must be highlighted, is the brass material which can be found in some connectors of the GBT Machine Station but which benefits from an exemption (copper alloy containing up to 4 % lead by weight - Annex III, §6.c of the RoHS Directive 2011/65/EU).

We also declare under our sole responsibility that the products:

Product name	Product Reference	Embedded radio module type	Starting from Serial Number
GBT Machine AIRFLOW Prophylaxis Master	FT-300	Bluetooth 5.0	MM00641
GBT Machine Wireless Pedal	EK-1055	Bluetooth 5.0	MN00268

are conforming with the essential and other relevant requirements of the RED Directive 2014/53/EU, especially, but not limited to the following standards and/or normative documents:

SAFETY

- IEC 60601-1:2005+AMD1:2012+AMD2:2020

EMC

- IEC 60601-1-2:2014+AMD1:2020
- ETSI EN 301 489-1 v2.2.3
- ETSI EN 301 489-3 v2.3.2

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- ETSI EN 301 489-17 v3.2.4
- ETSI EN 301 489-52 v1.2.1
- ETSI EN 300 330 v2.1.1

SPECTRUM

- ETSI EN 300 328 v2.2.2
- EN 301 908-1 v15.1.1
- EN 301 908-13 v13.2.1

Supplementary information
The Notified Body LCIE (Laboratoire Central des Industries Electriques), with the identification number 0081, performed a conformity assessment of the above-mentioned products using an EU-type examination followed by the conformity to type based on internal production control.
Then, he issued the EU-type examination certificate: N° 20314435-794299-A.

The complete Technical Construction File is kept available by E.M.S. Electro Medical Systems S.A.

Lieu, date	**Place, date**	**Ort, Datum**
	Nyon, 20.03.2025 Valid until: 16.12.2025	
Fonction, nom et signature	**Function, name and signature**	**Funktion, Name und Unterschrift**
Project/Product Manager	Renaud Vincent	..... Head of Product Management CBT
Head of Quality	Danielle Haffner	..... Head of Quality / RA.

Project Manager Samuel David

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Part 1 - Device

IUD-ID de base : **Basic UDI-DI :** 07613353058LM **Basic-UDI-DI :**

References of Class IIa that are compliant with Annex IX:

CE 0124

Liste de produits **Product list** **Produktliste**

References	DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII
FT-300	DEV	GBT Machine AIRFLOW Prophylaxis Master	IIa	9, part 1

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Part 2 - AIRFLOW Handpieces

IUD-ID de base : **Basic UDI-DI :** 07613353035L9 **Basic-UDI-DI :**

References of Class IIa that are compliant with Annex IX:

CE 0124

Liste de produits **Product list** **Produktliste**

References	DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII
EL-308#	ACC	AIR-FLOW handpiece 120°	IIa	5, part 4
EL-308/*	ACC	AIR-FLOW handpiece 120°	IIa	5, part 4
FS-465	ACC	AIRFLOW MAX Handpiece set	IIa	5, part 4

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

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Part 3 – PERIOFLOW Handpieces

IUD-ID de base : **Basic UDI-DI :** 07613353016L5 **Basic-UDI-DI :**

References of Class IIa that are compliant with Annex IX:

CE 0124

Liste de produits **Product list** **Produktliste**

References	DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII
EL-354#	ACC	PERIO-FLOW Handpiece	IIa	5, part 4
EL-354/*	ACC	PERIO-FLOW Handpiece	IIa	5, part 4
FS-474	ACC	PERIOFLOW Handpiece set	IIa	5, part 4

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

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Part 4 – PIEZON Handpieces

IUD-ID de base : **Basic UDI-DI :** 07613353021KW **Basic-UDI-DI :**

References of Class IIa that are compliant with Annex IX:

CE 0124

References	SET/DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII
EN-060#	ACC	PIEZON Handpiece LED	IIa	9
EN-060/*	ACC	PIEZON Handpiece LED	IIa	9
EN-061#	ACC	Piezon Handpiece	IIa	9
EN-061/*	ACC	Piezon Handpiece	IIa	9
FS-455	ACC	PIEZON Handpiece Set	IIa	9

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

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Part 5 – PERIOFLOW Nozzles

IUD-ID de base : **Basic UDI-DI :** 07613353036LB **Basic-UDI-DI :**

References of Class IIa that are compliant with Annex IX:

CE 0124

Liste de produits **Product list** **Produktliste**

References	DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII
DT-476	ACC	40x PERIO-FLOW nozzles marked	IIa	5, part 4
DT-476/US	ACC	40x PERIO-FLOW nozzles marked	IIa	5, part 4

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Part 6 – PIEZON Instruments

IUD-ID de base : **Basic UDI-DI :** 07613353037LD **Basic-UDI-DI :**

References of Class IIa that are compliant with Annex IX:

CE 0124

Liste de produits **Product list** **Produktliste**

References	DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII
DS-001A	ACC	Instrument A	IIa	5, part 4
DS-001A/T	ACC	Instrument A x3	IIa	5, part 4
DS-010A	ACC	File Holder 120°	IIa	5, part 4
DS-011A	ACC	Instrument P	IIa	5, part 4
DS-011A/T	ACC	Instrument P x3	IIa	5, part 4
DS-016A	ACC	Instrument PS	IIa	5, part 4
DS-016A/T	ACC	Instrument PS x3	IIa	5, part 4
DS-083A	ACC	Instrument PSL	IIa	5, part 4
DS-083A/T	ACC	Instrument PSL x3	IIa	5, part 4
DS-084A	ACC	Instrument PSR	IIa	5, part 4
DS-084A/T	ACC	Instrument PSR x3	IIa	5, part 4
DT-065A	ACC	Instrument PI	IIa	5, part 4
FS-295#	ACC	Instrument PI starter kit	IIa	5, part 4
FS-458	ACC	Instruments A P PS	IIa	5, part 4
FS-459	ACC	Instruments PS PSR PSL	IIa	5, part 4
FS-461	ACC	Instruments PSR PSL	IIa	5, part 4

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Part 7 - Pedals

IUD-ID de base : **Basic UDI-DI :** 07613353042L6 **Basic-UDI-DI :**

References of Class I that are compliant with Article 19 (self-declaration):

CE

Liste de produits **Product list** **Produktliste**

References	DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII
EK-1055	ACC	GBT Machine Wireless Pedal	I	1
EK-1055B	ACC	GBT Machine Wireless Pedal	I	1

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Part 8 - Dental Carts

IUD-ID de base : **Basic UDI-DI :** 07613353007L4 **Basic-UDI-DI :**

References of Class I that are compliant with Article 19 (self-declaration):

CE

Liste de produits **Product list** **Produktliste**

References	DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII
DW-100	ACC	GBT Machine Station	I	1

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Part 9 – GBT FLOWCONTROL

IUD-ID de base : **Basic UDI-DI :** 07613353059LP **Basic-UDI-DI :**

References of Class I that are compliant with Article 19 (self-declaration):

CE

Liste de produits **Product list** **Produktliste**

References	DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII
FV-112/A	ACC	GBT FLOWCONTROL x 4	I	5, part 1

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