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 FLOWCONTROL

Selon liste de produits (page 2) | According to product list (page 2) | Nach Produktliste (Seite 2)

Destination : | Intended purpose: | Zweckbestimmung :

Intended to provide high-volume oral evacuation and aerosol reduction during dental procedures.

IUD-ID de base : | **Basic UDI-DI:** | **Basis-UDI-DI :**

07613353059LP

satisfont aux dispositions applicables du règlement 2017/745 relatif aux Dispositifs Médicaux, Article 19 (auto-declaration). | **are conforming to the relevant provisions of the Medical Device Regulation 2017/745, Article 19 (self-declaration).** | **den einschlägigen Bestimmungen der Medizinprodukteverordnung 2017/745 entsprechen, Artikel 19 (Selbsterklarung) entsprechen.**

CE

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
SRN: FR-AR-000011266

Lieu, date | **Place, date** | **Ort, Datum**

Nyon, 06.03.2023

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

Project/Product Manager | Renaud Vincent | .....

Head of Quality | Timothée Deblock | .....

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GBT FLOWCONTROL

IUD-ID de base : **Basic UDI-DI :** 07613353059LP **Basis-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	CE market release date
FV-112/A	ACC	GBT FLOWCONTROL x 4	I	5 (part1)	06.03.2023
FV-112/A/AD	ACC	GBT FLOWCONTROL x4 w/adapter	I	5 (part1)	06.03.2023

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