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 :

N/A

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:

Stone catcher ACL

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

Destination : Intended purpose: Zweckbestimmung :

Accessories of LITHO products, intended for the fragmentation and removal of urinary tract calculi in the kidney, ureter, and bladder.

satisfont aux dispositions applicables du règlement 2017/745 relatif aux Dispositifs Médicaux. Procédure d'évaluation de la conformité : Annexes II & III (auto-déclaration)

are conforming to the relevant provisions of the Medical Device Regulation 2017/745. Conformity assessment pathway: Annexes II & III (self-declaration)

den einschlägigen Bestimmungen der Medizinprodukteverordnung 2017/745 entsprechen. Konformitätsbewertungsverfahren: Anhang II & III (Selbsterklärung)

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

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

Nyon, 2021-05-18

Fonction, nom et signature	**Function, name and signature**	**Funktion, Name und Unterschrift**
Project/Product Manager	Charles McCurrach	.....
Head of Quality	Timothée Deblock	.....

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

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

07613353050L5

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

CE

References	SET/DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII	CE market release date
FR-125	ACC	Stone catcher ACL	1	1	N/A

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

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