

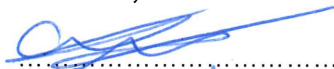

**DECLARATION DE CONFORMITE EU
EU DECLARATION OF CONFORMITY
EU-KONFORMITÄT SERKLÄRUNG**

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:

SWISS LITHOCLAST TRILOGY accessories

Selon liste de produits (page 2) Destination :	According to product list (page 2) Intended purpose: SWISS LITHOCLAST TRILOGY acesories are intended for the fragmentation and removal of urinary tract calculi in the kidney, ureter, and bladder.	Nach Produktliste (Seite 2) Zweckbestimmung :
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 Nyon, 2021-05-10	Ort, Datum
Fonction, nom et signature	Function, name and signature	Funktion, Name und Unterschrift
Product Manager	Charles McCurrach	
Head of Quality	Timothée Deblock	

Part 1 - Suction Bags

IUD-ID de base :

Basic UDI-DI :
07613353047LG

Basis-UDI-DI :

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

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

Official references	Logistic references	DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII	CE market release date
DT-480	N/A	ACC	Double suction bags set	I	2	12/2018
DT-481	N/A	ACC	Suction bags 5l	I	2	12/2018
M0068402061	DT-486	ACC	Double Suction Bags set	I	2	12/2018
M0068402071	DT-487	ACC	Suction bags 5l	I	2	12/2018

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

Part 2 - Torque Wrench

IUD-ID de base :

Basic UDI-DI :
07613353045LC

Basis-UDI-DI :

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

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

Official references	Logistic references	DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII	CE market release date
DT-492	N/A	ACC	TRILOGY probe torque wrench	I	1	12/2018
DT-492W	N/A	ACC	Torque wrench multiuse	I	1	12/2018
M0068403590	DT-492B	ACC	Swiss LithoClast Trilogy Reusable Torque Wrench	I	1	12/2018
DT-492BW	DT-492BW	ACC	Torque Wrench reusable BSC	I	1	12/2018

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

Part 3 - Steri Holder

IUD-ID de base :

Basic UDI-DI :
07613353044LA

Basis-UDI-DI :

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

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

Official references	Logistic references	DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII	CE market release date
FR-327	N/A	ACC	Steri holder Trilogy	I	1	12/2018
M0068401640	FR-327B	ACC	Steri Holder Trilogy	I	1	12/2018

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

Part 4 - Pedal

IUD-ID de base :

Basic UDI-DI :
07613353043L8

Basis-UDI-DI :

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

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

Official references	Logistic references	DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII	CE market release date
EK-386A	N/A	ACC	Foot pedal for SWISS LITHOCLAST TRILOGY	I	13	12/2018
M0068402050	EK-386B	ACC	Swiss LithoClast Trilogy Foot Switch	I	13	12/2018

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

Part 5 - Medical Cart

IUD-ID de base :

Basic UDI-DI :
07613353041L4

Basis-UDI-DI :

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

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

Official references	Logistic references	DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII	CE market release date
DW-047	N/A	ACC	Cart for Swiss Lithoclast TRILOGY	I	1	12/2018
M0068401760	DW-047B	ACC	Swiss Lithoclast Trilogy Cart	I	1	12/2018

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