

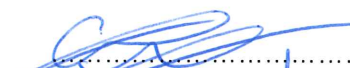

**DECLARATION DE CONFORMITE EU
EU DECLARATION OF CONFORMITY
EU-KONFORMITÄTSERKLÄRUNG**

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:

Carts & Pedals - Medical

Selon liste de produits (page 2)	According to product list (page 2)	Nach Produktliste (Seite 2)
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, 2021-05-10	
Fonction, nom et signature	Function, name and signature	Funktion, Name und Unterschrift
Project/Product Manager	Charles McCurrach	
Head of Quality	Timothée Deblock	

Part 1 – Medical Carts

IUD-ID de base :

Basic UDI-DI :
07613353041L4

Basis-UDI-DI :

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



Destination :

Intended purpose:

Zweckbestimmung :

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

Liste de produits

Product list

Produktliste

References	SET/DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII	CE market release date
DW-030	ACC	Cart Swiss LithoClast	I	1	2007-04-10
DW-038	ACC	All-In-One Cart	I	1	2012-10-01

Destination :

Intended purpose:

Zweckbestimmung :

The DOLOR devices are intended to be used for the treatment of various indications on the musculoskeletal system with radial Extracorporeal Shock Wave Therapy (rESWT), provided the affected parts of the body (tendons, muscles, bones, ligaments, nerves, skin) can be reached by and safely treated with the radial extracorporeal shock waves.

Liste de produits

Product list

Produktliste

References	SET/DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII	CE market release date
DW-040	ACC	Cart Swiss DolorClast Smart	I	1	2010-09-24
DW-044	ACC	Cart StackUp	I	1	2016-04-22
DW-055	ACC	Compact Cart DolorClast	I	1	2020-04-15
DW-1005	ACC	Cart DolorClast Laser	I	1	2020-05-08

Destination :

Intended purpose:

Zweckbestimmung :

The LASER Devices are intended for use in surgical procedures using open, laparoscopic and endoscopic for incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including urology and Urinary Lithotripsy.

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

References	SET/DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII	CE market release date
DW-038	ACC	All-In-One Cart	I	1	2012-10-01

Part 2 – Medical Pedals

IUD-ID de base :

Basic UDI-DI :
07613353043L8.

Basis-UDI-DI :

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



Destination :

Intended purpose:

Zweckbestimmung :

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

Liste de produits

Product list

Produktliste

References	SET/DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII	CE market release date
EK-166A	ACC	Foot pedal LithoClast Master 6m	I	13	N/A
EK-166B	ACC	Foot pedal LithoClast Master	I	13	N/A
EK-166DA	ACC	Electric foot pedal LithoClast Master-J	I	13	N/A
EK-216A	ACC	Electric footpedal	I	13	N/A
EK-278	ACC	Electric foot pedal	I	13	N/A

Destination :

Intended purpose:

Zweckbestimmung :

The DOLOR devices are intended to be used for the treatment of various indications on the musculoskeletal system with radial Extracorporeal Shock Wave Therapy (rESWT), provided the affected parts of the body (tendons, muscles, bones, ligaments, nerves, skin) can be reached by and safely treated with the radial extracorporeal shock waves.

Liste de produits

Product list

Produktliste

References	SET/DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII	CE market release date
EH-078	ACC	Pneumatic foot pedal	I	13	N/A
EK-223	ACC	Electrical foot pedal	I	13	N/A

Destination :

Intended purpose:

Zweckbestimmung :

The LASER Devices are intended for use in surgical procedures using open, laparoscopic and endoscopic for incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including urology and Urinary Lithotripsy.

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

References	SET/DEV/ACC	Product names	Class 2017/745/EEC Annex VIII	Rules 2017/745/EEC Annex VIII	CE market release date
EK-350	ACC	Foot pedal LaserClast	I	13	N/A