

CERTIFICATE

Number: 2240378

The management system of the organization(s) and locations mentioned on the addendum belonging to:

E.M.S. Electro Medical Systems S.A.

31 Chemin de la Vuarpilliere
1260 Nyon
Switzerland

Manufacturer Facility Identifier F004454

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia:	Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil:	RDC ANVISA n. 665/2022, 551/2021 and 67/2009
Canada:	Medical Devices Regulations - Part 1- SOR 98/282
Japan:	MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act
United States:	21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:

Design, manufacture, distribution and servicing activities of:

- Intracorporeal lithotripters, probes, handpieces, Laser fibers and suction systems for the area of urology;
- Extracorporeal shockwave therapy devices, handpieces and applicators for the area of orthopedics;
- Piezo ceramic devices, air abrasion devices, air polisher devices, handpieces, instruments, powders, nozzles and suction cannulas for the area of dentistry

Certificate expiry date: 2028-07-01
Certificate effective date: 2025-07-01
Certified since: 2019-09-23

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M. McKenzie
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed.

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
<https://www.dekra-checkme.com/org>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.



ADDENDUM

To certificate: 2240378

The management system of the organization(s) and/or location(s) of:

E.M.S. Electro Medical Systems S.A.

31 Chemin de la Vuarpilliere
1260 Nyon
Switzerland

Certified organization(s) and/or locations:

Different scope

E.M.S. Electro Medical Systems S.A.
Rte de Champ-Colin 2
1260 Nyon
Switzerland
Facility Identifier F006141

Manufacture activities of:

- Intracorporal lithotripters, probes, handpieces, Laser fibers and suction systems for the area of urology;
- Extracorporeal shockwave therapy devices, handpieces and applicators for the area of orthopedics;
- Piezo ceramic devices, air abrasion devices, air polisher devices, handpieces, instruments, powders, nozzles and suction cannulas for the area of dentistry

E.M.S. Electro Medical Systems S.A.
Rte de Champ-Colin 18
1260 Nyon
Switzerland
Facility Identifier F006142

Manufacture and logistic activities of:

- Intracorporal lithotripters, probes, handpieces, Laser fibers and suction systems for the area of urology;
- Extracorporeal shockwave therapy devices, handpieces and applicators for the area of orthopedics;
- Piezo ceramic devices, air abrasion devices, air polisher devices, handpieces, instruments, powders, nozzles and suction cannulas for the area of dentistry

E.M.S. Electro Medical Systems S.A.
Rte de Champ-Colin 10
1260 Nyon
Switzerland
Facility Identifier F006142

Logistics activities of:

- Intracorporal lithotripters, probes, handpieces, Laser fibers and suction systems for the area of urology;
- Extracorporeal shockwave therapy devices, handpieces and applicators for the area of orthopedics;
- Piezo ceramic devices, air abrasion devices, air polisher devices, handpieces, instruments, powders, nozzles and suction cannulas for the area of dentistry

Addendum expiry date: 2028-07-01

Addendum effective date: 2025-07-01