

# 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

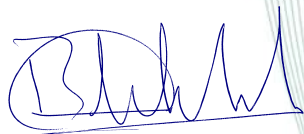
Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure  
Brazil: RDC ANVISA n. 665/2022, 551/2021 and 67/2009  
Canada: Medical Devices Regulations - Part 1- SOR 98/282  
Japan: MHLW Ministerial Ordinance 169, Article 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 and distribution of intracorporeal lithotriptors, probes, handpieces, and pumps for the area of urology; extracorporeal shockwave therapy systems for the area of orthopedics; piezo ceramic systems, air abrasion devices, air polisher devices, powders, nozzles and holders for the area of dentistry.

Certificate expiry date: 2025-07-01  
Certificate effective date: 2023-07-01  
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.A. 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-product-safety.com/en/certified-organizations>

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

Manufacturing of medical devices for dentistry, urology and orthopedics.

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

Manufacturing and logistic activities of medical devices for dentistry, urology and orthopedics.

Addendum expiry date: 2025-07-01  
Addendum effective date: 2023-07-01