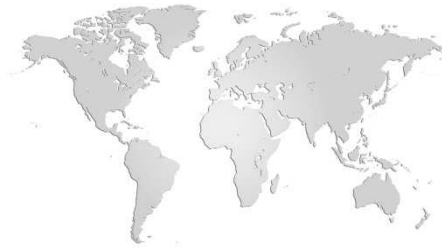


# EC CERTIFICATE

## for the Quality Assurance System



### according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company  
**E.M.S. Electro Medical Systems S.A.**

Chemin de la Vuarpillière 31, 1260 Nyon, Switzerland

**Certified location:**

Chemin de la Vuarpillière 31, 1260 Nyon, Switzerland  
E.M.S. Electro Medical Systems S.A., Rte. de Champ-Colin 2, 1260 Nyon, Switzerland  
E.M.S. Electro Medical Systems S.A., Rte. de Champ-Colin 18, 1260 Nyon, Switzerland  
E.M.S. Foncine S.A.S., Rte. de Pontarlier 32, 39460 Foncine-le-Haut, France

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50081-Z7-00, the decision dated 2020-06-15 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2020-06-15 to 2024-05-26

Registration No.: 50081-16-09



Ruth Delbeck-Bayer  
DEKRA Certification GmbH Stuttgart; 2020-06-15  
Notified Body ID-number: 0124



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
**ZLG-BS-295.10.02**



# Annex to the EC Certificate No. 50081-16-09

Valid from 2020-06-15 to 2024-05-26

Revision status of the annex: 0 dated 2020-06-15

Devices/device categories included in the certificate:

## Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

IntraCorporal Lithotripters systems  
- Stone Catcher

## Class II a:

IntraCorporal Lithotripters systems  
- Swiss LITHOPUMP  
- Probes (pneumatic, ultrasound and combined)  
- Probes Sets (pneumatic, ultrasound and combined)

Piezo-ceramic systems for dentistry - Piezon  
- PIEZON product group  
- PIEZON Surgery product group  
- PIEZON Handpieces, PIEZON instruments

Air abrasion / air polisher devices for dental prophylaxis  
- AIRFLOW product group  
- PERIOFLOW nozzles  
- AIRFLOW, PERIOFLOW Handpieces

Air abrasion / air polisher devices for dental prophylaxis with Piezo-ceramic systems for dentistry  
- AIRFLOW / PIEZON product group

Surgical HO\_YAG laser systems  
- SmartFibers product group

## Class II b:

IntraCorporal Lithotripters systems  
- LITHOCLAST product group  
- LITHOCLAST handpieces (pneumatic, ultrasound and combined)  
- Handpiece Sets (pneumatic, ultrasound and combined)

ExtraCorporal shock wave therapy systems  
- DOLORCLAST product group  
- DOLORCLAST Handpieces, DOLORCLAST applicators

Surgical HO\_YAG laser-system  
- Swiss LASERCLAST product group

  
Ruth Delbeck-Bayer



DEKRA Certification GmbH, Stuttgart, 2020-06-15  
Notified Body ID-number: 0124

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