

# CERTIFICATE

for the

## Quality Assurance System



As a notified body of the European Union (Reg. No. 0124) DEKRA Certification GmbH hereby approves the Quality Assurance System applied for design, manufacture and final inspection by the company

**E.M.S. Electro Medical Systems S.A.**  
Chemin de la Vuarpillière 31 • CH-1260 Nyon

**Production Sites:**

E.M.S. Electro Medical Systems S.A., Chemin de la Vuarpillière 31 • CH-1260 Nyon  
E.M.S. Electro Medical Systems S.A., Rte. de Champ-Colin • CH-1260 Nyon  
E.M.S. Foncine S.A.S., Rte. de Pontarlier • F-39460 Foncine-le-Haut

Approval is based on the result of the certification audit with report number 50081-Z3-00 and is performed in accordance with the stipulations of

### Annex II, Section 3 of the Directive 93/42/EEC

of the Council dated June 14, 1993 governing medical devices. The certification is applicable to the devices specified in the Annex. The devices in question are subjected to testing and examination in accordance with Annex II, Section 3 of the Directive 93/42/EEC. The listed devices may be affixed with the CE marking indicated below.



Date of the first certification: 13.11.1996

This certificate is valid until: 13.07.2011

Date of the last recertification: 14.07.2006

Certificate-registration No.: 50081-16-03  
**English version**

  
DEKRA Certification GmbH  
Stuttgart, 04.07.2006



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZQ-992.94.16

# Annex to the Certificate 50081-16-03 dated 04.07.2006

English version

Revision status: 1

Date: 05.05.2008

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## Devices/device categories included in the certificate

### Class II a:

- Lithotripsy accessories
- Piezo-ceramic systems for dentistry
- Air abrasion devices for dental prophylaxis
- Air abrasion accessories
- Total endoprosthesis (TEP) Revision system
- Joint revision osteotomes
- TEP revision system accessories
- TEP revision system sterile accessories

### Class II b:

- Intracorporal lithotriptors
- Lithotripsy accessories
- Sterile lithotripsy accessories
- Extracorporal shock wave therapy system



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