

EC CERTIFICATE
Full Quality Assurance System
 Directive 93/42/EEC on Medical devices, Annex II excluding (4)

No. 5-631-200-0911

**National Institute for Quality- and Organizational Development
 in Healthcare and Medicines**
Directorate of Device Testing and Clinical Engineering (EMKI)

certifies that the manufacturer:

EMED SP. Z O. O. SP. K.
ul. Ryżowa 69a
05 - 816 Opacz
Poland

for the products / product categories:

Electrosurgical units and accessories

applies a quality system which ensures that the products conform to the provisions of the Directive which apply to them at every stage from design to final inspection.

Registry number of the related audit report: **42-132-2007**

This Certificate is valid until: **2013-10-20** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by EMKI as a Notified Body for the Council Directive 93/42/EEC with identification number **1011**.

This certificate is valid only with the attachment.

Issue: 3

First issued: 2009-11-26

Budapest, 2012-02-24


 General Director




 Certification Office



EMKI 0630

The validity of the certificate is verifiable at EMKI.

Gyógyszerészeti és Egészségügyi Minőség- és Szervezetfejlesztési Intézet
National Institute for Quality- and Organizational Development in Healthcare and Medicines
Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering

EMKI

H-1125 Budapest, Diós árok 3.
 Tel.: +36 1 356 1522 Fax: +36 1 375 7253

Internet: : www.gyemszi.hu

ATTACHMENT TO EC CERTIFICATE

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Additional Information for Certificate Number 5-631-200-0911

The Certificate is valid for the following manufacturing site / facility:

EMED SP. Z O. O. SP. K.
ul. Ryzowa 69a
05-816 Opacz
Poland

The Certificate is valid for the following products:

Electrosurgical units:

ES 120, ES 300, ES 350, ES 400, ES ARGON, ES 350 with argon module,
ES 350 with argon and ThermoStapler®, ES VISION, SPECTRUM

Accessories:

Electrosurgical electrode, active electrode
Electrosurgical electrode, active electrode (sterile)
Electrosurgical electrode, active electrode, footswitch actuated
Electrosurgical electrode, active electrode, hand actuated
Electrosurgical electrode, active electrode, hand actuated (sterile)
Neutral electrodes for HF-surgery

The detailed description of the products is kept by EMKI under No. 42-132-2007

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