



# LIGER MEDICAL

## EC DECLARATION OF CONFORMITY FULL QUALITY ASSURANCE PROCEDURE

**Manufacturer:**

Liger Medical, LLC | [www.LigerMedical.com](http://www.LigerMedical.com)  
3300 North Running Creek Way,  
Building G, Suite 020  
Lehi, UT 84043, USA  
Office: 801.256.6576

**European Authorized Representative:**

SMIDGEN  
Millhouse, Bleach Road  
Kilkenny, Eire  
Ireland

**Product Name:**

Electrical Surgical Generator  
Electrical Cautery Generator  
Handheld Thermocoagulator Device

**Model Number(s):**

ESU-110  
ECU-110  
HTU-110

**Conformity Assessment Route**      MDD via Annex II/ ISO 13485

**Classification**

The Electrical Surgical and Electrical Cautery Generators are considered a Class IIb, and the Handheld Thermocoagulator is considered a Class IIa, Active Medical Device per MDD 93/42/EEC, Annex IX, Rule 9

**Scope of Application:**

Design, development, manufacturing, sales and distribution of medical devices for women's healthcare including electrosurgical generators, electrocautery instruments, and thermal ablation devices for cervical cancer

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the Essential Requirements, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

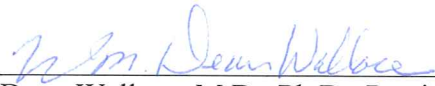
**Full Quality Management System Certificate:**


Annex II MDD 93/42/EEC  
CE Mark Certification number: TBD

**Standards Applied:**

ISO 13485:2003 - Certification number: FM 668782

**Authorized Signatory:**

  
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Dean Wallace, M.D., Ph.D., President

  
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Date