LIGER MEDICAL

EC DECLARATION OF CONFORMITY
FULL QUALITY ASSURANCE PROCEDURE

Manufacturer:
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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:

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

March 3, 2017
Date