144484-14-03-28

EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

CE Certiso Ltd., Organisation for Certification and Testing on the Field of Medical and Hospital Engineering (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

WON TECH Co., Ltd.

Headquarters: **64 Techno 8-ro, Yuseung-gu, Daejeon, KOREA**

Authorised representative: **DONGBANG AcuPrime®**
1 The Forrest Units, Hennock Road East Exeter, EX2 8RU, UK

Scope:

Focused Ultrasound Stimulator System

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
Focused ultrasound stimulator system with imaging module	Ultra Skin	Non-invasive coagulation and lifting of the skin.	-	II.a
Focused ultrasound stimulator system	Ultra Skin II ULTRA LADY	Non-invasive coagulation and lifting of the skin.	-	II.a

This certificate is valid only in case of successfully conducted annual surveillance audits.

ID number of the related audit report: **73-CE-140108**

Issue: 1
Issued: 28 March 2014
First issued: 28 March 2014
Start date of certified status: 28 March 2014

Expires:
23 February 2019

CE Certiso
Orvos- és Kórháztechnikai
Ellenőrző és Tanúsító Kft.
H-2040 Budaörs, Gyár u. 2.
Adószám: 23147049-2-13

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