SGS

EC Certificate Full Quality Assurance System: KR08/01160

The management system of

Chungwoo Co., Ltd.

#614 Woolim-Lionsvally II 680, Gasan-dong, Geumcheon-gu, Seoul, Korea

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 4 April 2013 until 22 October 2016 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 22 May 2013 Issue 11. Certified since 22 October 2008

Certification is based on reports numbered KR/SEL Y-PC/08183

Authorised by



SGS United Kingdom Ltd, Notified Body 0120

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Chungwoo Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 11

Detailed scope

Low frequency stimulator (Model: CWM-601, CWM-530, CWM-402);

Low frequency stimulator with ultrasound (Model: CWM-540);

Low frequency stimulator with heating (Model: CLS-3400, CLS-3300);

Radio frequency stimulator (Model: CWM-901, CWM-902, CWM-900);

Ultra-sound stimulator (Model: CWM-302).

Ultrasound Cavitation Stimulator (Model: CWM-510)

Fractional RF Surgical Unit with Sterile single-use Micro Needle

(Model: CWM-930).

Multifunctional RF Stimulator (Model: CWM-920).

Thermal Vacuum Massager (Model: CWM-504)

For placing on the market of Class III devices covered by this certificate, an EC Design Examination

Certificate according to Annex II (Section 4) is required.