

EC DECLARATION OF CONFORMITY

Manufacturers: REMED Co., Ltd.
 #301~303 Migun Techno World II, 187, Techno 2ro, Yuseong-gu, Daejeon,
 305-500, Korea
 Tel. +82-42-934-5560

EC Representative: FinLink
 Myllärintie 10/76, 00920 Helsinki, FINLAND
 TEL. +358 44 511 5324

Product Name: Extracorporeal Shock Wave Therapy Equipment (ESWT)

Brand Name: ROSETTA - main unit and standard accessories:
 ESWT-GUN (S) - small applicator
 ESWT-GUN (L) - large applicator

Classification: Class II b (according to Rule 9)

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC AS AMENDED BY 2007/47/EC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

"Conformity Assessment Route : Annex II (excluding Section 4), Full Quality Assurance System)"

Standards applied:

EN 60601-1:2006/AC:2010,
 EN 60601-2-10:2000/A1:2001
 EN 60601-1-2:2007/AC:2010

Notified Body: BSI

Place, Date of Issue: Republic of Korea / Dec, 18th, 2014

Signature:



Geun-Young Lee
President
 On behalf of REMED

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.

CE 612074

Issued To:

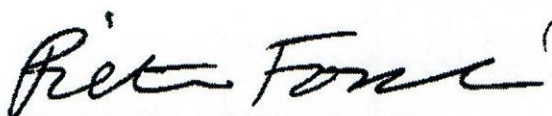
**Remed Co., Ltd.
301~303, Migun Techno World II
187, Techno 2-ro
Yuseong-gu
Daejeon
305-500
Republic of Korea**

In respect of:

The design and manufacture of Electromagnetic Stimulator, Transcranial Magnetic Stimulator, Electrosurgical Unit, Laser Therapy and Extracorporeal Shock Wave Therapy Equipments.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Pietro Foschi - Strategic Delivery Director

First Issued: **13 June 2014**

Date: **18 December 2014**

Expiry Date: **14 December 2019**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 612074**
 Date: **18 December 2014**
 Issued To: **Remed Co., Ltd.**
301~303, Migun Techno World II
187, Techno 2-ro
Yuseong-gu
Daejeon
305-500
Republic of Korea

Subcontractor:

Service(s) supplied

FinLink
 Myllärintie 10/76
 Helsinki
 00920
 Finland

EU Representative

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EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 612074**
Date: **18 December 2014**
Issued To: **Remed Co., Ltd.**
301~303, Migun Techno World II
187, Techno 2-ro
Yuseong-gu
Daejeon
305-500
Republic of Korea

Date	Reference Number	Action
13 June 2014	8124691	First issue, transfer from ITC Certificate numbers: 13 1055 QS/NB, 09 0900 QS/NB/a, 11 0293 QS/NB and 11 0045 QS/NB.
12 September 2014	8194881	Addition of Electrosurgical Unit to Scope of Certificate due to transfer of CE Certificate from ITC Certificate number: 13 0902 QS/NB.
18 December 2014	8124694	Certificate Renewal

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