REMED

CE
0086

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 Rout : 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**

bsi.

By Royal Charter

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, Transcraniel 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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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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