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
34025
Republic of Korea

In respect of:

The design and manufacture of Electromagnetic Stimulator and Transcranial Magnetic Stimulator.

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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2014-06-13** Date: **2020-02-28** Expiry Date: **2024-05-26**

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Supplementary Information to CE 612074

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Class IIb		
GMDN	**Device name**	**Intended purpose as per IFU**
12415	Transcranial Magnetic Stimulator TAMAS	The device is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from one prior antidepressant medication or above the minimal effective dose and duration in the current episode.
12415	Transcranial Magnetic Stimulator ALTMS-A	The device is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from one prior antidepressant medication or above the minimal effective dose and duration in the current episode.
12415	Transcranial Magnetic Stimulator ALTMS	The device is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from one prior antidepressant medication or above the minimal effective dose and duration in the current episode.

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Class IIa		
NBOG code	**Device name**	
MD1103	Electromagnetic stimulator SALUS-TALENT	---
MD1103	Electromagnetic stimulator SALUS-TALENT-Pro	---
MD1103	Electromagnetic stimulator SALUS-TALENT-A	---
MD1103	Electromagnetic stimulator emField Pro	---
MD1103	Electromagnetic stimulator SALUS-TALENT-Pro-Aes	---

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List of Significant Subcontractors

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

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Subcontractor:	**Service(s) supplied**
FinLink Myllärintie 10/76 Helsinki 00920 Finland	**EU Representative**
Remed Co., Ltd. R&D center 84, Osongsaengmyeong 2-ro Osong-eup, Heungdeok-gu Cheongju-si Chungcheongbuk-do 28161 Republic of Korea	**Design**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 612074**

Date: **2020-02-28**

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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
13 June 2017	8718606	Certificate re-issue. Addition of Model List. Change of postal code from"305-500" to "34025".
01 October 2018	9634795	Certificate re-issue due to addition of product model emField Pro and ALTMS-A
27 February 2019	8870541	Traceable to NB 0086.
Current	3144238	Certificate renewal with the following changes Deletion of product categories Electrosurgical Unit, Laser Therapy and Extracorporeal Shock Wave Therapy Equipments. Deletion of Model List. Addition of product list. Addition of R&D center as design facility.