REMED
Rehabilitation Medical Company

CE 2797

# EC DECLARATION OF CONFORMITY

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| MANUFACTURER: | **REMED Co., Ltd.**<br>#301-303, migun Techno World II, 187, Techno-2ro, Yuseong-gu, 34025, Daejeon-si, Korea<br>Tel. +82-42-934-5560 |
| EUROPEAN REPRESENTATIVE: | **FinLink**<br>Myllärintie 10/76, 00920 Helsinki, FINLAND<br>Tel. +358 44 511 5324 |
| COMMON/GENERIC NAME: | Electromagnetic Stimulator |
| TRADE/PROPRIETARY NAME: | SALUS-TALENT-A |
| CLASSIFICATION: | Class IIa by Rule 9 of Annex IX of Medical Device Directive 93/42/EEC |
| CONFORMITY ASSESSMENT ROUTE: | Annex II (excluding Section 4.),<br>Full quality assurance system |

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC AS AMENDED BY 2007/47/EC (MDD) FOR MEDICAL DEVICES AND DIRECTIVE 2011/65/EU (ROHS 2). ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

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| STANDARDS APPLIED: | EN 60601-1:2006+A1:2013, Medical electrical equipment. General requirements for basic safety and essential performance<br>EN 60601-1-2:2015, Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests<br>EN 60601-2-10:2001, Medical electrical equipment. Particular requirements for the safety of nerve and muscle stimulators<br>BS EN 62304:2006+A1:2015, Medical device software. Software life-cycle processes.<br>MEDDEV 2.7.1 Rev. 4, Clinical Evaluation: A guide for manufacturers and notified bodies under directive 93/42/EEC and 90/385/EEC |
| NOTIFIED BODY: | **BSI Group The Netherlands B.V.**<br>Say Building John M. Keynesplein 9 1066 EP Amsterdam |
| NOTIFIED BODY Number: | **2797** |
| (EC) CERTIFICATE(S): | CE 612074<br>*(Issue date: 28/02/2020, Valid date: 26/05/2024)* |
| NBOG CODE: | MD1103 (Electromagnetic Stimulator) |
| PLACE, DATE OF ISSUE:<br>VALID DATE | Republic of Korea, 02/03/2020<br>Valid Date: 31/12/2020 |
| SIGNATURE: |  <br>Mr. Geun-Yong Lee / PRESIDENT |