



EC DECLARATION OF CONFORMITY

MANUFACTURER: **REMED Co., Ltd.**
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Tel. +82-42-934-5560

EUROPEAN REPRESENTATIVE: **FinLink**
Myllärintie 10/76, 00920 Helsinki, FINLAND
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COMMON/GENERIC NAME: Electromagnetic Stimulator

TRADE/PROPRIETARY NAME: SALUS-TALENT-Pro

CLASSIFICATION: Class IIa by Rule 9 of Annex IX of Medical Device Directive 93/42/EEC

CONFORMITY ASSESSMENT ROUTE: Annex II (excluding Section 4.),
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.

STANDARDS APPLIED: EN 60601-1:2006+A1:2013, Medical electrical equipment. General requirements for basic safety and essential performance
EN 60601-1-2:2015, Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests
EN 60601-2-10:2001, Medical electrical equipment. Particular requirements for the safety of nerve and muscle stimulators
BS EN 62304:2006+A1:2015, Medical device software. Software life-cycle processes.
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.**
Say Building John M. Keynesplein 9 1066 EP Amsterdam

NOTIFIED BODY Number: **2797**

(EC) CERTIFICATE(S): CE 612074
(Issue date: 28/02/2020, Valid date: 26/05/2024)

NBOG CODE: MD1103 (Electromagnetic Stimulator)

PLACE, DATE OF ISSUE: Republic of Korea, 02/03/2020
VALID DATE Valid Date: 31/12/2020

SIGNATURE:

Mr. Geun-Yong Lee / PRESIDENT