REMED
Rehabilitation Medical Company

CE 2797

EC DECLARATION OF CONFORMITY

MANUFACTURER:	**REMED Co., Ltd.** #301-303, migun Techno World II, 187, Techno-2ro, Yuseong-gu, 34025, Daejeon-si, Korea Tel. +82-42-934-5560
EUROPEAN REPRESENTATIVE:	**FinLink** Myllärintie 10/76, 00920 Helsinki, FINLAND Tel. +358 44 511 5324
COMMON/GENERIC NAME:	Electromagnetic Stimulator
TRADE/PROPRIETARY NAME:	SALUS-TALENT
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: VALID DATE	Republic of Korea, 02/03/2020 Valid Date: 31/12/2020
SIGNATURE:	 Mr. Geun-Yong Lee / PRESIDENT

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