REV-MED
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EC Declaration of Conformity

We herewith declare under our sole responsibility that following products meet the provisions of the Council Directive 93/42/EEC and amended by 2007/47/EC concerning medical devices.

Product Name:	Therapeutical Laser Unit
Model Name:	Hilthera 4.0
Relevant EC Directives:	Medical Device Directive 93/42/EEC amended by Directive 2007/47/EC
Conformity Assessment Route:	Annex II excluding Section 4
Classification:	Class IIb according to Rule 9 of Annex IX of 93/42/EEC
GMDN Code	60409 Musculoskeletal/physical therapy laser, professional
Applied Standards:	refer to annex 1
CE Certificate no.:	2195-MED-2012004
Valid until:	2024-05-25
Manufacturers Registered Name:	**REV-MED Inc.**
Manufacturers Registered Address:	#304, 464, Dunchon-daero, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea Tel: +82 31 741 0996
EC Representative Name:	**REV-MED International GmbH**
EC Representative Address:	Einsteinstr.167, 81677 Munich, Germany Tel: +49 89 237 625 40, Fax: +49 89 237 625 41
Notified Body:	**Szutest Uygunluk Değerlendirme A.Ş** Tatlısu Mahallesi Akif İnan Sk. No:1/1 Ümraniye / İstanbul T: +90 216 469 46 66 (Notified Body Identification no.: 2195)
Start of CE-Marking:	2020-04-29

Date: 2020-05-07

CEO of REV-MED Inc.
Shin BongGeun
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Annex 1

No.	Harmonized Standard	Application
1	IEC 60601-1:2005 +A1:2012	Medical electrical equipment – Part 1: General requirement for basic safety and essential performance
2	EN 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3	IEC 60601-2-22:2007 +A1:2012	Medical electrical equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
4	IEC 61000-3-2:2014	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
5	IEC 61000-3-3:2013	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection
6	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
7	EN 1041:2008	Terminology, Symbols and Information provided with Medical Devices - Information supplied by the manufacturer with medical devices
8	EN ISO 15223-1:2016	Graphical symbols for use in the labeling of medical devices
9	EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
10	MEDDEV 2.12/2 Rev.2	Post Market Clinical Follow-up Studies
11	MEDDEV 2.7/1 Rev.4	Clinical Evaluation: A guide for manufacturers and notified bodies
12	MEDDEV 2.12/1 Rev.8	Guidelines on a Medical Devices Vigilance System
13	EN 62304:2006	Medical device software - Software life cycle process
14	ISO 7010:2011	Graphical symbols – Safety colors and safety signs – Registered safety signs
15	IEC 62348/TR Ed. 1.0	Mapping between the clauses of the third edition of IEC 60601-1 and the 1998 edition as amended
16	IECEE OD-2044-Ed.1.0	Guidance for the evaluation of risk management in medical electrical equipment
17	EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
18	EN 62366:2008	Medical devices - Application of usability engineering to medical devices
19	IEC 60825-1:2007	Safety of laser products - Part 1: Equipment classification and requirements
20	EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
21	EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
22	EN ISO 10993-10:2013	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.