# EC DECLARATION OF CONFORMITY

**according to the Medical Device Directive 93/42/EEC**

The undersigned, Robert Lai , representing WELL-LIFE Healthcare Limited/ 6F., No. 168, Lide St., Jhonghe District, New Taipei City, 23512, Taiwan ; the supplier declares that the equipment described hereafter:

| -Product Clarification | -Well-Life Model No. | -PROMED GmbH |
|---|---|---|
| -WL-210xy Series<br>Well-Life Tens | -WL-2103A | -WL-2103A<br>TENS 1000S |

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- **Medical Device Directive 93/42/EEC**
- **The European Standard EN 60601-1: 2006-Safety of medical device; Electrical equipment -General safety.**
- **The European Standard EN 60601-1-2: 2015 -Medical-Electrical Safety-Electromagnetic Compatibility.**
- **The International Standard EN 60601-2-10:2015 -Medical Electrical Equipment; Part 2-10: Particular requirements for the safety of nerve and muscle stimulator.**
- **The European Standard EN 60601-1-6:2010 -Medical Electrical Equipment; Part 1-6:General requirement for safety-Collateral standard: Usability.**
- **The European Standard EN 60601-1-11:2015 -Medical Electrical Equipment; Part 1-11:General requirement for safety-Collateral standard: Requirement for the medical electrical equipment used in home healthcare.**
- **The International Standard EN ISO 14971: 2019 -Medical devices -Application of risk management.**
- **The International Standard EN ISO 13485: 2016 -Medical Device -Quality management requirements.**
- **The European Standard EN 1041: 2008-Terminology, Symbols and Information provided with medical device -Information supplied by the manufacturer with medical device.**
- **The European Standard EN ISO 15223-1: 2016 -Medical devices -Symbols to be used with medical devices labels, labelling and information to be supplied; Part 1: General requirements.**
- **International Standard EN ISO 10993-1: 2009; Biological evaluation -Part I: Guidance on selection of tests.**
- **International standard EN ISO 10993-5:2009; Biological evaluation -Part 5: Tests for in vitro cytotoxicity.**
- **International standard EN ISO 10993-10:2010; Biological evaluation -Part 10: Tests for irritation and delayed-type hypersensitivity .**
- **The International Standard EN 62304:2006 -Medical device software-Software life cycle processes.**
- **The International Standard EN 62366:2008 -Medical device-Application of Usability Engineer**

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| **Certificate** | **MDSAP** | **Certificate No.TW20/99034** | **Valid until 2023-08-02** |
| | **ISO 13485:2016** | **Certificate No.TW09/00359** | **Valid until 2024-07-08** |
| | **CE certificate (Directive 93/42/EEC)** | **Certificate No.TW09/00361** | **Valid until 2023-08-07** |

EC REP

MDSS GmbH
Schiffgraben 41
0175 Hannover, Germany

Notified Body
SGS Belgium NV.Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium

CE 1639

Signature: Robert Lai

Qualification: General Manager

Date: June 02,2023

**6F., No. 168, Lide St., Jhonghe District , New Taipei City 23512 , Taiwan**
**Tel: + 886-2-2928 2112 Fax: +886-2-2928 1880**