EU DECLARATION OF CONFORMITY

Manufacturer:	**I.A.C.E.R. S.r.l** **Via Enzo Ferrari 2 – 30037 Scorzè (Ve), Italia**
SRN (Single Registration Number):	**IT-MF-000009126**

The Manufacturer declares under his own responsibility that the product:

Description:	**PEMF Therapy device**
Model:	**LAMAGNETO PRO**
Basic UDI-DI:	**8019781PEMFLFDEVP2**
UDI-DI:	**08019781101075**
Batch number:	
S/N:	

is compliant with the following Union harmonization legislation:

Union harmonization legislation:	**Regulation (EU) 2017/745 of the Parliament and of the Council of April 5th 2017 relating to medical devices, and further modifications.**
Intended use:	**PEMF therapy device studied and indicated for the rehabilitation and functional recovery treatments of pathologies affecting:** • **wrist, hand, shoulder, foot, ankle and knee joints;** • **skeletal motor system;** • **muscular atrophies and dystrophies;** • **contusions;** • **distortions;** • **benign injuries and muscle tears;** **and for the care treatments of:** • **osteoporosis;** • **bone edema;** • **osteonecrosis;** • **ulcers;** • **neuropathies;** • **arthrosis;** • **bursitis;** • **periarthritis;** • **tendonitis and tendinosis.** **The device is also particularly suitable for the treatment of fractures and consolidation delays.**

I.A.C.E.R. Srl Via Enzo Ferrari 2 - 30037 Scorzè (VE) - Italy **T** +39 041 5401356 **PEC** iacer@pec.it
VAT N./P.IVA/C.F. IT00185480274 **SDI** SUBM70N **Share Capital/Capitale Sociale**: € 1.000.000 fully paid-up/interamente versato
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Risk class:	**IIa, in accordance to regulation 9 of Annex VIII of Regulation (EU) 2017/745 and subsequent modifications**
Applied technical standards:	**EN 60601-1:2006/A2:2021, EN 60601-1-2:2015/A1:2021, EN 60601-1-11:2015, EN 60601-1-6:2010+A1:2015, EN ISO 14971: 2019/A11:2021, EN ISO 10993-1: 2020, EN ISO 10993-5: 2009, EN ISO 10993-10: 2013, EN ISO 10993-18:2020, EN ISO 15223-1:2021, EN ISO 20417:2021, EN 62304:2006/A1:2015, EN ISO 62366-1:2015+AMD1:2020, AAMI TIR57:2016/(R) 2019, AAMI TIR97:2019, ISTA 2A**
Applied common specifications:	**N/A**
Notified Body:	**1936 – TÜV Rheinland Italia S.r.l..** **Via Mattei, 3 – 20005 Pogliano Milanese (MI) - Italia**
Conformity assessment procedure applied:	**Annex IX, Chapter I**
EU Certificate of Conformity: Issuance date: Expiration date:	**ITH 1344294 1** **16/01/2023** **15/01/2028**
Additional information:	**The device does not incorporate as an integral part any substance or derivative of human blood referred to in point 8 of article 1 of the above mentioned regulation;** **No fabrics of animal origin have been used in the production as per Regulation (EU) 722/2012 of the Commission;** **The device has no measuring functions nor is it sterile.**

Union harmonization legislation:	**Directive 2011/65/EU of the European Parliament and of the Council of June 8th 2011, on the restriction of the use of certain hazardous substances in electrical and electronic equipment, as modified by the Delegated Directive 2015/863/EU of the Commission of March 31st 2015, and further modifications.**

Union harmonization legislation:	**Directive 2014/53/EU of the European Parliament and of the Council of April 16th 2014 on the harmonization of the legislations of the Member States relating to the making available on the market of radio equipment.**
Brand:	**I-TECH MEDICAL DIVISION, WEPERE**
Accessories and components supplied:	**Power supply** **Model: UES36LCP1-150200SPA**

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	Input: AC 100-240V, 50/60Hz, 1.0A **Output: DC 15.0V, 2.0A, 30.0W** **DC cable: 140 cm unshielded**
HW version:	**V1.1**
SW version:	**V1.3**
Applied technical standards:	**Article 3.1a:** EN 60601-1:2006/A2:2021 EN 62479:2010 **Article 3.1b EMC:** EN 301 489-1 V2.2.3 EN 301 489-17 V3.2.4 **Article 3.2 Radio Spectrum:** EN 300 328 V2.2.2
Additional information:	The conformity of the devices in question with the essential requirements of Directive 2014/53/EU has been verified and certified by the Notified Body **2906 – SGS North America, Inc.** Certificate n°: **NB2906.2024.000010** In accordance with Module B of Annex III of Directive 2014/53/EU.

Signed in the name and on behalf of: **I.A.C.E.R. S.r.l.**

Place and date of issue: **Scorzè (VE), 31/01/2025**

Signature: 

Name and function: **Matteo Zennaro, CEO**

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