EU DECLARATION OF CONFORMITY

I.A.C.E.R. S.r.l

Via Enzo Ferrari, 2 – 30037 Scorzè (Ve), Italy

SRN (Single Registration Number): IT-MF-000009126

herewith declares under its own responsibility, that the product

Osteomat

Basic UDI-DI: 8019781PEMFLFMATPX

UDI-DI: 08019781112507

Batch no.:

Series no.:

is a professional 8 solenoids mattress for low frequency PEMF therapy. It is compatible with low frequency PEMF therapy devices of MAG2000 and LaMagneto families. Such devices are studied and indicated for the rehabilitation and functional recovery treatments of pathologies affecting:

- wrist, hand, shoulder, foot, ankle and knee joints;
- skeletal motor system;
- arthrosis;
- bunions;
- contusions;
- degeneration of the musculoskeletal system;
- distortions;
- periarthritis;
- benign injuries and muscle tears;
- tendonitis and tendinosis.

All the devices in the family are particularly suitable for the treatment and cure of osteoporosis and all pathologies affecting bone tissues.

Osteomat complies with the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 relating to medical devices, which amends directive 2001/83/EC and repeals directives 90/385/ EEC and 93/42/EEC of the Council.

The device is classified as class I, in accordance with regulation 1 (4.1) of Annex VIII to this Regulation and meet all applicable standards and the general safety and performance requirements of the Regulation (EU) 2017/745 Annex 1.

The devices comply with the following applicable 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 62366-1:2015+A1:2020, EN ISO 14971:2019/A11:2021, ISO/TR 24971:2020, EN ISO

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PEC: iacer@pec.it - Web: www.itechmedicaldivision.com - Cod. Fisc./P.IVA/VAT N.: IT00185480274
R.E.A.: VE N. 120250 - M. VE001767 - Codice SDI/SDI Code: SUBM70N - Cap. Soc.: € 1.000.000,00 i.v.

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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.

It is also claimed that:

- the devices do not incorporate as an integral part any substance or derivative of human blood referred to in point 8 of article 1 of this regulation;
- no fabrics of animal origin have been used in the production as per Regulation (EU) no. 722/2012 of the Commission;
- no common specifications other than the standards mentioned above apply.

It also declares the conformity of the aforementioned products by issuing this EU Declaration of Conformity after having drawn up the technical documentation referred to in Annexes II and III of Regulation (EU) 2017/745 pursuant to article 52 (7) of the Regulation (EU) 2017/745.

Scorzè, 31/01/2023

Place, date

MASSIMO MARCON

Legal Representative

I.A.C.E.R. Srl
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