EU DECLARATION OF CONFORMTIY

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

TAP HF

Basic UDI-DI: 8019781PEMFHFTAPPE

UDI-DI: 08019781113412

Batch no.:

Series no.:

is designed and indicated for the treatment, rehabilitation and functional recovery of pathologies affecting:

- Wrist, hand, shoulder, foot, ankle and knee joints,
- Skeletal motor system,
- Muscular atrophies and dystrophies,
- Bunions,
- Bruises,
- Degeneration of the locomotor system,
- Distortions,
- Periarthritis,
- Benign injuries and muscle tears,
- Tendonitis and tendinosis.

It is designed to treat the spine area by placing it on the back of a chair or armchair.

It 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 + A1:2013, EN 60601-1-2:2015, EN 60601-1-11:2015, EN 60601-1-6:2010+A1:2015, EN 62366-1:2015, EN ISO 14971:2019, ISO/TR 24971:2020, EN ISO 10993-1:2009 + AC:2010, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 15223-1:2021, EN ISO 20417:2021.
It is also claimed that:

I.A.C.E.R. Srl
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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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- 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, 31/01/2022

Place, date

MASSIMO MARCON

Legal Representative

I.A.C.E.R. Srl
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