EU DECLARATION OF CONFORMITY

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

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

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

herewith declares under its own responsibility, that the product

I-PRESS ARM1 L

UDI-DI: 08019781900203

Basic UDI-DI: 8019781CLTH4CDEVDT

Batch no.:

Series no.:

is a pressotherapy designed for the treatment of diseases affecting the circulatory system, in order to improve peripheral blood circulation. The applications provided for this type of device are:

- Edemas
- Lymphedema
- Venous ulcers
- Venous insufficiency
- Muscle recovery

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

The device is classified as class IIa, in accordance with regulation 9 (6.1) 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, and bear the mark

CE 1936

Compliance of the concerned product with the Regulation (EU) 2017/745 and subsequent modifications has been assessed and certified by the Notified Body

I.A.C.E.R. Srl
Via Enzo Ferrari 2 - 30037 Scorzè (VE) – Italia/Italy - Tel.: (+39) 041/5401356 - Email: iacer@iacer.it
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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1936 – TÜV Rheinland Italia S.r.l.
Via Mattei 3, 20005 Pogliano Milanese (MI), Italia
Certificate No: ITH 1344294 1

following the certification procedure according to the Regulation (EU) 2017/745 and subsequent modifications, Annex IX.

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+A1:2021, EN 60601-1-6: 2010+A2:2021, 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 10993-23:2021 EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 62366-1:2015+AMD1:2020, ISTA 2A.

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 and subsequent modifications.

Scorzè, 22/03/2024
Place, date

MASSIMO MARCON
Legal Representative

I.A.C.E.R. Srl
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