EC DECLARATION OF CONFORMTIY

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

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

herewith declares under its own responsibility, that product

T-ONE REHAB

UMDNS Code: **13762**

Batch no.:

Series no.:

complies with the essential safety requirements of the European Medical Device Directive 93/42/EEC (transposed in Italy by the D.Lgs. 46/97), as modified by the Directive 2007/47/EC (D.Lgs.37/2010) and further modifications/integrations and with the requirements of art.120(3) of Regulation (EU) 2017/745 of the European Parliament and of the Council of the 5 April 2017 and subsequent modifications.

The product has been assigned to class IIa, according to Annex IX, rule 9 of the Directive 93/42/EEC (and further modifications/integrations) and bears the mark

CE 0068

Compliance of the concerned product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

0068 – MTIC InterCert S.r.l.

Via G. Leopardi 14, Milano (MI) 20123, Italia

Certificate no.: **0068/QCO-DM/234-2020**

following the certification procedure according to Annex II (excluding point 4) of the Directive 93/42/EEC.

The devices comply with the following applicable standards:

EN 60601-1:2006 + A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010 + A1:2015, EN 60601-1-11:2015, EN 60601-2- 10:2015, EN ISO 14971: 2019, ISO/TR 24971:2020, EN ISO 10993-1:2009+AC:2010, EN ISO 10993-5: 2009, EN ISO 10993-10: 2013, IEC 62133-1:2017, EN 62304:2006+A1:2015, EN 62366-1:2015.

It is also claimed that:

- The devices do not incorporate, as an integral part, any substance or a human blood derivate of point 10 of Annex 1 (Directive 2007/47/CE);
- No fabrics of animal origin have been used in the production as per Regulation (EU) no. 722/2012 of the Commission.

MASSIMO MARCON

Scorzè, 07/10/2024

Place, date

Legal Representative

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