
EC DECLARATION OF CONFORMITY

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

Via S.Pertini 24/A – 30030 Martellago (Ve), Italia

herewith declares under its own responsibility, that the product

ORTHOMAG

UMDNS Code: **12415**

Batch no.:

Series no.:

comply 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.

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



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/230-2020**

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, IEC 60601-1-6:2013, EN 60601-1-11:2015, EN ISO 14971: 2012, ISO 10993-1:2009+AC:2010, ISO 10993-5: 2009, ISO 10993-10: 2010, 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 derivative of point 10 of Annex 1 (Directive 2007/47/CE);
- tissue of animal origin, provided for in Directive 2003/32/CE, haven't been used in production.

Martellago, 19/06/2020

Place, date

MASSIMO MARCON

Legal Representative

I.A.C.E.R. Srl

Via S. Pertini 24/A - 30030 Martellago (VE) - Italy

Tel.: (+39) 041/5401356 - Fax: (+39) 041/5402684 - Email: iacer@iacer.it - PEC: iacer@pec.it - Web: www.itechmedicaldivision.com

Vat Number: IT00185480274 - R.E.A.: VE N. 120250 - M. VE001767 - Share Capital: € 110.000,00 i.v.

MD117-05 Date.Rev.20/12/19