

EC DECLARATION OF CONFORMITY

According to Council Directive 93/42/EEC, Annex VII

We,

BORCAD Medical a.s., based in Fryčovice 673, 739 45, Czech Republic,
ID company No.: 05342341

Incorporated in the Register of Companies by the Regional Court in Ostrava,
file number B 10855

as a producer of the medical device

Name: **Birthing bed**

Type designation: **AVE 2**

Model designation: **PPB** (Models are specified in the technical documentation of the product)

Specified purpose of use: **Birthing bed serves for woman (para) before and during giving birth and after giving birth.**

Classification of the medical device: **Class I** nonsterile, without measuring function, according to Annex IX MDD 93/42/EEC – rule 12

declare herewith that properties of the product mentioned meet Essential requirements of the Medical Device Directive, 93/42/EEC as amended by European Parliament and Council 2007/47/EC. The product's characteristics comply with applicable specific requirements in regulation (EC) No 1907/2006 and in directives: 2006/42/EC, 2011/65/EU. Evaluation of conformity was carried out according to Annex VII of Council Directive 93/42/EEC as amended.

The product mentioned complies with the following harmonized standards, which were used for assessing of conformity: ČSN EN 60601-1 ed. 2:2007, ČSN EN 60601-1-2 ed. 3:2016, IEC / EN 60601-2-52:2009, IEC / EN 60601-1-6 ed. 3:2010, IEC / EN 62366:2007, ČSN EN ISO 13485:2012, ČSN EN ISO 14971:2012, ČSN EN ISO 10993-1:2009, ČSN EN ISO 10993-5:2009, ČSN EN ISO 10993-10:2013

In Fryčovice, date: 17th March 2017



Martin Těšitel, Executive director



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Rev: 01/2017/PE