

## DECLARATION OF CONFORMITY

issued

according to section 13 paragraph 2 of Act no. 22/1997 Coll., on technical requirements for products, as amended (hereinafter "Act no. 22/1997 Coll."), in conjunction with Government Regulation no. 54/2015 Coll., on technical requirements for medical devices, as amended (hereinafter the "Government Regulation no. 54/2015 Coll.).

**Legal manufacturer:** RESI Třeboň spol. s r.o.

**Registered address:** Novohradská 1153, 379 01 Třeboň, Czech Republic

**ID:** 25178989

hereby confirms that the medical device:

### JORDAN AS

is in compliance with requirements for safety of medical devices laid down by Act no. 22/1997 Coll. and technical regulations in a manner consistent conformity assessment procedures set out in Government Regulation no. 54/2015 Coll.,

### and declares

that the characteristics of the medical device mentioned above meet all essential requirements set out in Government Regulation no. 54/2015 Coll. and that the medical device during its normal use is safe. Manufacturer also declares that he took measures to ensure conformity of all packages of the medical device mentioned above placed on the market with the essential requirements and the manufacturer's technical documentation.

#### **Variants of the medical device:**

- JORDAN AS

**The intended purpose of the medical device:** The tables are designed for use in medical facilities such as couches for rehabilitation and physiotherapy. The tables can also be used for the needs of ambulatory surgery for surgery without anesthesia, the patient is fully conscious.

The tables are intended for use in potentially explosive environments they are not suitable for use in the presence of flammable mixtures of anesthetic and air, or flammable mixture of anesthetics and oxygen, or nitrous oxide.

**Risk class:** In accordance with section 6 paragraph 1 point. a) Act no. 268/2014 Coll., on medical devices and amending Act no. 634/2004 Coll., on administrative fees, as amended, the medical device mentioned above is classified in accordance with Annex no. 9 of Government Regulation no. 54/2014 Coll. in risk class I.

**Medical device's sterility:** The medical device mentioned above is placed on the market as a NON-STERILE device.

**Measuring function:** The medical device mentioned above is placed on the market as a NON-MEASURING device.

**During conformity assessment were used:**

- Annex no. 7 of Government Regulation no. 54/2015 Coll. (Directive 93/42/EEC, as amended by Directive 2007/47/EC)
- manufacturer's technical file
- Quality Management System Standard ISO 9001

In Třeboň, date 1. 4. 2016

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**Ing. Jiří Šimeček**  
**RESI Třeboň spol. s r.o.**

