MZ Liberec, a.s.

The Manufacturer has systems certified according to
CSN EN ISO 9001, CSN EN ISO 13485 ed. 2, CSN EN ISO 14001, CSN OHSAS 18001

EC DECLARATION OF CONFORMITY

issued on the basis of Act 22/1997, Section 13 (2), or pursuant to Section 7 (1) of Government Regulation No. 54/2015 Coll.

This Declaration of Conformity is issued on the Manufacturer's sole responsibility.

CE

Declaration No.:	**EPS 712/COM i**
Name of the Manufacturer of DoC subject:	MZ Liberec, a.s.
Address of the Manufacturer of DoC subject:	No. 4, 543 72 Rudník, Czech Republic
DoC subject:	Stands with Compact, Spring-balanced, Tilting, and Rotating Arms in the following types: **SPR10-1, SPR10-2, SPR10-3, SPR10-4, SPR10-1W SPR11-1, SPR11-2, SPR11-1W**

The above described subject(s) conform(s) to the requirements set forth in the following documents:

Document number	Title	Issue/Issue date
Act No. 22/1997 Coll.	On technical requirements for products	NOTE 1
Act No. 268/2014 Coll.	On medical devices	NOTE 1
Government Regulation No. 54/2015 Coll.,	Technical requirements for medical devices	NOTE 1
93/42/EEC	Council Directive concerning medical devices	NOTE 1
CSN EN ISO 11197 ed. 2	Medical supply units	NOTE 1
CSN EN 60601-1 ed. 2	Medical electrical equipment. Part 1: General requirements for safety	NOTE 1

6) Additional information:

Classification of DoC subject:

- **pursuant to Appendix 9 of Government Regulation No. 54/2015 Coll.**, (corresponding to Council Directive 93/42/EEC (Appendix IX), this is a **medical device of class I**, non-sterile, without measuring functions
- **According to the criteria for electrical equipment**: Permanently installed electrical equipment of Class I protection, type B, intended for permanent operation but not intended for use in the presence of combustible mixtures of anaesthetics with oxygen, air, or other oxidizers.

Conformity assessment procedure:

The Manufacturer assessed the conformity using the procedure under Government Regulation No. 54/2015 Coll., Section 4(1), and elaborated the EC Declaration of Conformity according to Appendix 7, which corresponds to the procedure under Annex VII. of Council Directive 93/42/EEC. Certificate No. 1190381/2019 issued by EZÚ, s. p. (Electrotechnical Testing Institute) was used by the manufacturer for the purpose of conformity assessment.

The Manufacturer elaborated the Risk Analysis for the DoC subject in accordance with CSN EN ISO 14971.

NOTE 1: All legislation and standards stated above are in the wording valid as of the date of approval of the last revision of this document.

NOTE 2: This document is subject to a change procedure without previous notification.

Ing. Tomáš Potoček
Director and CEO

In Rudník, date of approval of the latest revision: 02. 07. 2019 Ver. No. 0311/11