MZ Liberec, a.s.
U Nisy 362/6
460 01 Liberec 3
Czech Republic

Member of the Association of Manufacturers and Suppliers of Medical Products and Member of the Association of industrial Gases
Tel.: +420 48 8040 111, Fax.: +420 48 8040 326,
Company Reg No: 47306581 Tax Reg No: CZ 47306581 E-mail.: info@mzliberec.cz

The manufacturer has a certified quality system according to ČSN EN ISO 9001 and ČSN EN ISO 13485

EC DECLARATION OF CONFORMITY

issued on the basis of paragraph (2) Section 13 of Act No 22/1997 Coll., or in accordance with paragraph (3) Section 4 of National Regulation No 336/2004 Coll.

CE

1) Declaration Number: **EPS 715**

2) Name of the manufacturer of the subject of the declaration: MZ Liberec, a.s.
Address of the manufacturer of the subject of the declaration: U Nisy 362/6, 460 01 Liberec 3, CZ

3) Subject of the declaration: PORTABLE STAND,
type: SPZ 13

4) The aforementioned items conform to the requirements of the following documents:

5) Document number	Title	Issued/Date of issue
Act No 22/1997 Coll.	about technical requirements placed on products	COMM. No 1
Act No 123/2000 Coll.	about medical products	COMM. No 1
National Regulation 336/2004 Coll.	technical requirements placed on medical products	COMM. No 1
Article 4.2, 4.11, 5.7, 5.9, 7, 8, 9.1, 9.3, 9.4, 9.8.1, 11.1, 11.6, 11.8, 13 and 15 of standard ČSN EN 60601-1 ed.2	Electric medical devices – Part 1: General requirements for basic safety and essential function	COMM. No 1

6) Supplementary information:

Classification of the subject of this declaration:

- pursuant to Government Regulation No 336/2004 Coll. this concerns Class I Medical Devices, non-sterile, non-invasive and without metering functions

Conformity assessment procedure:
The issuer of the declaration, who is also the manufacturer of the subject of the declaration, has a certified complete quality system by notified party No 1014 (certificate number MED090049).
The manufacturer assessed conformity by procedure according to Government Regulation No 336/2004 Coll., Section 9 paragraph (4) EC declaration of conformity according to Annex No 7, which corresponds to the procedure according to Annex VII. of Guideline 93/42/EEA.

Certificate number 1140767 /2014 issued by the Electrotechnical Testing Institute in Prague was used to assess conformity.

The manufacturer prepared an AR 715 Risk Analysis in accordance with ČSN EN ISO 14971 for the subject of the declaration.

COMM. No 1: All the quoted legal and normative regulations are as amended on the date of approval of the last review of this document
COMM. No 2: This document is subject to modification proceedings without prior notice.

Author: Bc. Libor Halama
modification No: 0013/11

7) **Approved by:**

Mgr., Ing. Martin Hájek
Chairman of the Board of Directors

Kateřina Shejbalová, DiS.
Head of the Development Macroprocess and Technical Preparation of Production (TPV)

Date of issue:
19/09/2014