



MZ Liberec, a.s.

The Manufacturer has systems certified according to
ČSN EN ISO 9001, ČSN EN ISO 13485

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.



Declaration No.: EPS 715 c
Manufacturer: MZ Liberec, a.s.
Address: Rudník 4, 543 72 Rudník u Vrchlabí, Czech Republic
DoC subject: Mobile Stand in the following types:
SPZ 13, SSP 13 – m, SSP 13 – v

The above described subject(s) of the declaration conform(s) to the requirements of the following documents:

Document No.	Title	Issue/Issue Date
Act 22/1997 Coll.	on technical requirements for products	NOTE 1
Government Regulation No. 118/2016 Coll., on the conformity assessment of electrical equipment	Designed for use within certain voltage limits when made available on the market	NOTE 1
2011/65/EU, No. 2015/863/EU on the restriction of the use of certain hazardous substances	in electrical and electronic equipment	NOTE 1
Sec. 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 ČSN EN 60601-1 ed.2:2007 + A1:2014.	Medical electrical equipment Part 1: General requirements for basic safety and essential performance	NOTE 1
ČSN EN ISO 14971	Medical devices – Application of risk management to medical devices	NOTE 1

Additional information:

Classification of DoC subject: The Mobile Stands are **electrical equipment of Class I protection**, without applied parts, with Protection IP20, intended for permanent operation in medical environment in the areas for general or special application.

Conformity assessment procedure: The Manufacturer assessed the conformity on the basis of Act No. 90/2016 Coll., Section 6(2), on the conformity assessment of specified products when made available on the market, and elaborated the EU Declaration of Conformity for the Mobile Stands in accordance with Section 4(2) of Government Regulation 118/2016 Coll.

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

CEO MZ Liberec, a. s.

Date of last revision: 02. 07. 2019

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