MZ Liberec, a.s. Member of Association of Manufacturers and Suppliers of Medical Equipment and
U Nisy 362/6 Member of Association of Technical Gases
460 01 Liberec 3 Czech Republic Phone: +420 488 040 111, Fax: +420 488 040 326, VAT: CZ473 065 81

The manufacturer has a quality management system in accordance with EN ISO 9001: 2009 and EN ISO 13485: 2003

CE 1014

EC Declaration of Conformity
(in compliance with EN ISO/IEC 17050-1/2011)

1) Declaration Reference : **EPS 712/COM b**

2) Declaration Issuer : **MZ Liberec, a.s.**

Declaration Issuer´s Address : U Nisy 362/6, 460 01 Liberec 3, Czech Republic

3) Product(s) of Declaration: ceiling pendants with compact, spring balanced, tilting and swiveling arms

Manufactured in types as follows: SPR10-1, SPR10-2, SPR10-3, SPR10-1W, SPR11

4) The above mentioned products are in a full compliance with requirements contained in the subsequent documents.

	Document Reference	Title	Issuance/Issue Date
5)	Act. 123/2000 Coll.	Medical Devices - Act	Note No.1
	Gov. Decree 336/2004 Coll.	Technical Requirements on Medical Devices	Note No.1
	EN ISO 11197:2009	Medical Power Units	Note No.1

6) Additional Information:

Classification of declared product(s):

- **as per Gov. Decree No. 336/2004 Coll.** that complies with Directive 93/42/EEC - **Medical devices, class I** (see Enclosure No.9, Rules No.1), non-sterile, free of measuring functions
- **as per standards applicable for electric equipment(s):** The firmly installed electric appliances, protection class I, type B, intended for permanent operation, non-usable whenever flammable mixtures of anaesthetics with oxide, air and/or other oxidizers are present on-site.

Procedure of conformity appraisal:
The declaration Issuer who is simultaneously the manufacturer of the declared product(s), has the fully certified quality system issued by the notified body No. 1014 (Certificate No. MED090049). **The manufacturer assessed the conformity** via procedure listed in Gov. Decree No. 336/2004 Coll., §9 section.(3) letter a) - EC Declaration of Conformity as per enclosure No.2 that corresponds to the procedure listed in Annex II, Medical Device Directive 93/42/EEC. The manufacturer elaborated the Risk Analysis covering the declared product(s) as per EN ISO 14971.

Note No.1: All stipulated legal and normative regulations to be understood in wording s valid in the day when the last and latest revised option of the document concerned was approved.

Note No.2: This document is subject to the amend announcement without prior notice.

Prepared by: Mr. Libor Halama, BC

Revised by: Mr. Libor Halama, BC

Dipl.- Ing. Martin Hájek
Chairman of Board of Directors

Dipl.- Ing. Jan Čmelík
R & D Director

7) Approved:

Last Option Approved on August 10, 2012