

EC Declaration of Conformity



General applicable: MDD 93/42/EEC

Council directive 93/42 EEC of 14 June 1993 concerning medical devices

Name of the Manufacturer: Shanghai Huifeng Medical Instrument Co., Ltd.

Address of the Manufacturer: No 7753 Chuannanfeng Highroad, Datuan Town, Pudong

District, 201311 Shanghai, China

Product:

- Shadowless Operating Lamp
- Cold Light Operating Lamp

Classification : Class I (MDD, Annex Ix) RULE: All non-invasive devices are in Class I.

We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

Standards:

- EN 980-2003
- EN 1041-1998
- EN ISO 14971-2000
- IEO60601-1
- IEO60601-2-41
- EN60601-1
- EN60601-2-4
- Complies with the requirement set out the Consolidated version of directive 93/42/EEC, Text of directive and amendments 93/42/EEC (medical devices). The Low Voltage Directive (LVD) 2006/95/EC and Directive 2004/108/EC (electromagnetic compatibility).

All applicable harmonized Standards (published in the Official Journal of the European Communities)

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