

# EC Declaration of Conformity

**Manufacturer:** Nanjing Mindray Bio-Medical Electronics Co., Ltd.  
666# Middle Zhengfang Road, Jiangning, 211100 Nanjing, Jiangsu, P.R.China

**EC-Representative:** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestrasse 80, 20537 Hamburg, Germany  
(DIMDI No.: DE/0000040627)

We, the manufacturer, herewith declare that the following indicated products and their accessories meet the provisions of Directive 93/42/EEC and the applied standards (including harmonized standards) described in the technical documentation associated with the product concerned. Refer to the attachment for details of the accessories and consumables of these products. All supporting documentations are retained under the premises of the manufacturer.

Product Name	Models	UMDNS Code
Medical Supply Unit	HyPort 3000, HyPort 6000, HyPort 8000, HyPort 9000, HyPort B30, HyPort B80	18046
Operating Table	HyBase 3000, HyBase 6100, HyBase 8300, HyBase 8500, UniBase 30	13961
LED Surgical Light	HyLED 9500; HyLED 9700; HyLED 8600; HyLED 9500M; HyLED 8600M; HyLED 760; HyLED 730; HyLED 760M; HyLED 730M; HyLED 600; HyLED 600M; HyLED 9500/9500; HyLED 9700/9500; HyLED 9500/8600; HyLED 9700/8600; HyLED 9700/9700; HyLED 8600/8600; HyLED 9500/9500/9500; HyLED 9700/9500/9500; HyLED 9700/9700/9500; HyLED 9700/9700/9700; HyLED 8600/8600/8600; HyLED 9500/8600/8600; HyLED 9500/9500/8600; HyLED 9700/8600/8600; HyLED 9700/9500/8600; HyLED 9700/9700/8600; HyLED 760/760; HyLED 760/730; HyLED 730/730; HyLED 760/760/760; HyLED 760/760/730; HyLED 760/730/730; HyLED 730/730/730; HyLED 600/600;	12347
Surgical Light	HyLite 6500; HyLite 6700; HyLite 6500/6500; HyLite 6700/6500; HyLite 6700/6700; HyLite 6500/6500/6500; HyLite 6700/6500/6500; HyLite 6700/6700/6500; HyLite 6700/6700/6700	
LED Examination Light	HyLED200; HyLED200M; HyLED200/200;	12347

Compliance of the LED Surgical Light, Surgical Light and Operating Table as well as their accessories with the Directive 93/42/EEC have been assessed following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

The LED Surgical Light, Surgical Light , Examination light and Operating Table as well as their accessories have been assigned to class I by rule 12 according to Annex IX of the Directive 93/42/EEC. And these products bear the mark



The above declaration about Medical Supply Unit is based on the certification of full quality assurance system according to Annex II, Article 3 of Directive 93/42/EEC.

Compliance of the Medical Supply Unit with the Directive 93/42/EEC has been assessed following the procedure relating to the EC Declaration of Conformity set out in Annex II, Article 3 of Directive 93/42/EEC and has been certified by the Notified Body.

**TÜV SÜD Product Service GmbH**

**Ridlerstraße 65, 80339 MÜNCHEN, Germany**

**Certificate No.: G1 15 11 70744 006**

**Issue date: 23.1.2016    Expiry date: 22.1.2021**

The Medical Supply Unit has been assigned to class IIb by rule 11 according to Annex IX of the Directive 93/42/EEC. It bears the mark



This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices. Any modification of the medical device not authorized by the manufacturer will invalidate this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of Nanjing Mindray Bio-Medical Electronics Co., Ltd.

**Signature:**

*Li Xiaoqiao*

**Place, Date of Issue:**

Nanjing, 2016-11-22

**Name of Authorized Signatory:**

Mr. Li Xiaoqiao

**Position Held in Company:**

Management Representative