



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 under our sole responsibility the following indicated products meet the provisions of Directive 93/42/EEC and the applied standards (including harmonized standards). All supporting documentations are retained under the premises of the manufacturer.

Product Name	Models	GMDN Code	UMDNS Code
LED Surgical Light	HyLED X9; HyLED X5; HyLED X9/X5; HyLED X5/X5; HyLED X9/X9; HyLED X9/X9/X9; HyLED X9/X9/X5; HyLED X9/X5/X5; HyLED X9M; HyLED X90; HyLED X50; HyLED X90/X50; HyLED X50/X50; HyLED X90/X90; HyLED X90/X90/X90; HyLED X90/X90/X50; HyLED X90/X50/X50; HyLED X90M; 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; HyLED9700/9700; HyLED 8600/8600; HyLED 9500/9500/9500; HyLED 9700/9500/9500; HyLED 9700/9700/9500; HyLED 9700/9700/9700; HyLED 8600/8600/8600; HyLED760/760; HyLED760/730; HyLED730/730; HyLED760/760/760; HyLED760/760/730; HyLED760/730/730; HyLED 730/730/730; HyLED600/600;	37332	12282
LED Examination Light	HyLED200; HyLED200M;	12276 36843	12276

Classification: I (According to Annex IX, Rule 12 of Directive 93/42/EEC)

Conformity Assessment Route: Annex VII of Directive 93/42/EEC

Standards Applied:

EN ISO 13485:2016/ISO 13485:2016	EN ISO 14971:2012/ISO 14971:2007
EN 60601-1-6:2010/IEC 60601-1-6:2010	EN ISO 15223-1:2016
EN 60601-1-2: 2015 / IEC 60601-1-2:2014	EN 1041:2008
EN 60601-2-41:2009+A11:2011/IEC 60601-2-41:2009	EN 62366:2008/IEC62366:2007
EN 60601-1:2006+A1:2013/IEC 60601-1:2005+A1:2012	EN 62304:2006+AC:2008

Signature:

Li Xiaoqiao

Place, Date of Issue:

Nanjing, 2019-04-30

Name of Authorized Signatory:

Mr. Li Xiaoqiao

Position Held in Company:

Management Representative