



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)

Product Name: Operating Table

Model: HyBase 3000, HyBase 6100, HyBase 8300, HyBase 8500, UniBase 30

UMDNS Code: 13961 **GMDN Code:** 35379

Classification: I (According to Annex IX, rule 1 of the Directive 93/42/EEC)

Conformity Assessment Route: MDD Annex VII

Supplementary Information: Operating Table Accessories Including but not limited to: Clamp, Anesthesia Screen Holder, Arm Board, Leg Support, Foot Plate, Body Support, Shoulder Support, Body Strap, Cassette Fixer, Pad for disc operations, Table Padding, Universal Adaptor, Orthopedic Extension Device, Head Rest, Drainage Bowl, etc.

We, the manufacturer, herewith declare that under our sole responsibility the following indicated product meets all the provisions of Directive 93/42/EEC which apply to them.

Standard Applied:

EN ISO 13485:2016/ ISO 13485:2016
EN 60601-1:2006+A1:2013/IEC 60601-1:2005+A1:2012
EN 60601-1-2:2015/IEC 60601-1-2:2014
EN ISO 14971:2012 / ISO 14971:2007
EN ISO 10993-1:2009 /ISO 10993-1:2009
EN 60601-2-46:2011
EN 1041:2008

Place, Date of Issue: Nanjing, 14.03.2019

Signature:

Name of Authorized Signatory: Mr. Li Xiaoqiao

Position Held in Company: Management Representative