CE 0123

EC Declaration of Conformity

Manufacturer: Nanjing Mindray Bio-Medical Electronics Co., Ltd.
666# Middle Zhengfang Road, Jiangning, 211111 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 all the provisions of Directive 93/42/EEC and Directive 2006/42/EC which apply to them.

Product Name: Medical Supply Unit

Model: HyPort 3000, HyPort 3500, HyPort 6000, HyPort 6500, HyPort 8000, HyPort 9000, HyPort B20, HyPort B30, HyPort B60, HyPort B80

UMDNS Code: 18046 GMDN code: 35630

Classification: IIb (According to Annex IX, rule 11 of the Directive 93/42/EEC)

Compliance of the designated product(s) with the directives 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 070744 0017 Rev. 00

Issue date: 5.3.2020 Expiry date: 26.5.2024

The designated product(s) is compliant with the following standards and/or other normative documents for which documented evidence for compliance:

EN ISO 13485:2016/ISO 13485:2016

EN60601-1:2006+AC:2010/IEC60601-1:2005+COR.1:2006 +COR.2:2007+A1:2012;

EN 60601-1-2:2015/IEC 60601-1-2:2014 EN 1041:2008;

EN 60601-1-6:2010/IEC 60601-1-6：2010; EN 62366：2008/IEC 62366:2007;

EN ISO 11197:2009/ ISO 11197:2004; EN ISO 14971:2012/ ISO 14971:2007;

EN ISO 9170-1:2008/ ISO 9170-1:2008; EN ISO 9170-2:2008/ ISO 9170-2:2008;

The above mentioned declaration is based on the certification of full quality assurance system according to Annex II, Article 3 of Directive 93/42/EEC. All supporting documentations are retained under the premises of the manufacturer.

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.

Place, Date of Issue: Nanjing, 2020-7-10

Signature: Yu Zhiyang

Name of Authorized Signatory: Mr. Yu Zhiyang

Position Held in Company: Manager, Technical Regulation

Digitally signed by Prodan Sveatoslav
Date: 2021.04.16 17:36:46 EEST
Reason: MoldSign Signature
Location: Moldova