Declaration of Conformity-V5.0

Declaration of Conformity CE 0123

Manufacturer:	Shenzhen Mindray Scientific Co., Ltd. 6/F, Bldg 2, 1203 Nanhuan Avenue, Yutang Block, Guangming District, Shenzhen, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany
Product:	Infusion pump (Including Accessories)
Model:	BeneFusion VP1, BeneFusion VP1 Ex, BeneFusion VP3, BeneFusion VP3 Ex
Classification:	IIb（According to Rule 11 of MDD Annex IX）
GMDN Code:	13215
MD Code	MD 1101
Conformity Assessment Route:	MDD Annex Ⅱ excluding (4)

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Device, as amended by 2007/47/EC. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München, Germany
Notified Body No. :	0123
Place, Date of Issue:	Shenzhen, 20.9.1.2
Signature:	Bai Yanhong
Name of Authorized Signatory:	Bai Yanhong
Position Held in Company:	Manager, Technical Regulation

Digitally signed by Prodan Sveatoslav
Date: 2022.06.24 17:23:49 EEST
Reason: MoldSign Signature
Location: Moldova

Attachment of Declaration of Conformity: Applied Standards List-V2.0

Product:	Infusion pump
Model:	BeneFusion VP1, BeneFusion VP1 Ex, BeneFusion VP3, BeneFusion VP3 Ex

Applied Standards:

EN 60601-2-24:2015	Medical electrical equipment -- Part 2-24: Particular requirements for the safety of infusion pumps and controllers
EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-8:2007/A1:2013	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN 60601-1-6:2010/A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 60601-1-2:2015	Medical Electrical Equipment - Part 1-2 General Requirements for Safety - Collateral Standard: Electromagnetic compatibility-Requirements and tests
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 15223-1: 2016	Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements
EN 1789:2007+A2:2014	Medical vehicles and their equipment - Road ambulances