

Declaration of Conformity-V5.0

Declaration of Conformity



Manufacturer: Shenzhen Mindray Scientific Co., Ltd.
6/F, Bldg 2, 1203 Nanhuan Avenue, Yutang Block, Guangming District,
518106 Shenzhen, P. R. China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, Germany

Product: Syringe pump (Including Accessories)

Model: BeneFusion SP1, BeneFusion SP1 Ex, BeneFusion SP3,
BeneFusion SP3 Ex, BeneFusion SP3D, BeneFusion SP3D Ex

Classification: IIb (According to Rule 11 of MDD Annex IX)

GMDN Code: 13217

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, 2019.1.2

Signature:

Name of Authorized Signatory: Bai Yanhong

Position Held in Company: Manager, Technical Regulation

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

Product:	Syringe pump
Model:	BeneFusion SP1, BeneFusion SP1 Ex, BeneFusion SP3, BeneFusion SP3 Ex, BeneFusion SP3D, BeneFusion SP3D 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