Declaration of Conformity

CE 2797

Manufacturer:	Shenzhen Mindray Scientific Co., Ltd. 6/F, Bldg 2, 1203 Nanhuan Avenue, Yutang Block, Guangming District, 518106 Shenzhen, P. R. China
Manufacturer SRN:	CN-MF-000030037
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany
EC-Representative SRN:	DE-AR-000000001
Product:	Syringe pump (Including Accessories)
Model:	BeneFusion nSP, BeneFusion nSP ex, BeneFusion nSP Neo BeneFusion eSP, BeneFusion eSP ex, BeneFusion eSP Neo
Bisic UDI DI	69469888AB01600030X7
Classification:	IIb（According to Rule 12 of MDR Annex VIII）
Conformity Assessment Route:	Annex IX
GMDN Code:	13217
EMDN Code:	Z12030302
Intended Purpose:	The syringe pump is intended for controlling the dose of liquid infused into the patient's body.

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS:	/
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
Notified Body No. :	2797
Identification of the Certificate:	MDR 761396 R000
Start of CE-Marking:	2020.05.23

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of Shenzhen Mindray Scientific Co., Ltd., Effective immediately.

Place, Date of Issue:	Shenzhen, 2025.9.22
Signature:	Li Lei
Name of Authorized Signatory:	Li Lei
Position Held in Company:	Manager, Technical Regulation

Digitally signed by Alexa Gheorghe
Date: 2026.05.28 16:14:07 EEST
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ

Attachment of Declaration of Conformity: Applied Standards List-V3.0

Product:	Syringe pump
Model:	BeneFusion nSP, BeneFusion nSP ex, BeneFusion nSP Neo BeneFusion eSP, BeneFusion eSP ex, BeneFusion eSP Neo

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+A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-8 AMD2:2020	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
IEC 62366-1:2015+AMD1:2020	Medical devices - Application of usability engineering to medical devices
IEC 60601-1-6:2010+AMD1:2013+AMD2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
IEC 60601-1-2:2014+AMD1:2020	Medical Electrical Equipment - Part 1-2 General Requirements for Safety - Collateral Standard: Electromagnetic compatibility-Requirements and tests
EN ISO 20417:2021	Information supplied by the manufacturer of medical devices
ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements
EN 1789:2020+A1:2023	Medical vehicles and their equipment - Road ambulances; German version
EN 13718-1:2014+A1:2020	Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances