Declaration of Conformity V3.0

Declaration of Conformity

CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
Manufacturer SRN:	**CN-MF-000014156**
EC-Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany
Product:	Needle-guided bracket
Model:	NGB-001、NGB-002、NGB-003、NGB-005、NGB-006、NGB-007、NGB-011、NGB-012、NGB-015、NGB-016、NGB-018、NGB-019、NGB-020、NGB-022、NGB-023、NGB-024、NGB-026、NGB-029、NGB-031、NGB-032、NGB-034、NGB-035、NGB-036、NGB-037、NGB-039、NGB-040、NGB-042、NGB-043、NGB-044、NGB-052、NGB-053、NGB-054、NGB-056、NGB-057、NGB-058、NGB-059、NGB-060、NGB-063、NGB-055、NGB-064
Basic UDI-DI:	69449040AB050100355Y
Classification:	I (According to Rule 1 of MDR Annex VIII)
Conformity Assessment Route:	Article 52.7
GMDN code:	58248
EMDN code:	A018002

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:	/
Identification of the Certificate:	/
Start of CE-Marking:	**2023-03-21**

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 Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue:	Shenzhen, 2025-10-13
Signature:	
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Deputy Director, Technical Regulation

Declaration of Conformity V3.0

Declaration of Conformity

CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
Manufacturer SRN:	**CN-MF-000014156**
EC-Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany
Product:	Needle-guided bracket
Model:	NGB-004、NGB-009、NGB-010、NGB-021、NGB-025、NGB-027、NGB-045、NGB-047、NGB-048、NGB-051、NGB-062、NGB-065
Basic UDI-DI:	69449040AB050100355Y
Classification:	I (According to Rule 5 of MDR Annex VIII)
Conformity Assessment Route:	Article 52.7
GMDN code:	58248
EMDN code:	A018002

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:	/
Identification of the Certificate:	/
Start of CE-Marking:	**2023-03-21**

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

Place, Date of Issue:	Shenzhen, 2025-10-13
Signature:	
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Deputy Director, Technical Regulation

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

Applied Standards List

Product:	**Needle-guided bracket**
Model:	NGB-001、NGB-002、NGB-003、NGB-004、NGB-005、NGB-006、NGB-007、NGB-009、NGB-010、NGB-011、NGB-012、NGB-015、NGB-016、NGB-018、NGB-019、NGB-020、NGB-021、NGB-022、NGB-023、NGB-024、NGB-025、NGB-026、NGB-027、NGB-029、NGB-031、NGB-032、NGB-034、NGB-035、NGB-036、NGB-037、NGB-039、NGB-040、NGB-042、NGB-043、NGB-044、NGB-045、NGB-047、NGB-048、NGB-051、NGB-052、NGB-053、NGB-054、NGB-056、NGB-057、NGB-058、NGB-059、NGB-060、NGB-062、NGB-063、NGB-055、NGB-064、NGB-065

Standards Applied:

EN ISO 14971:2019/A11:2021	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part1: General requirements
EN 60601-1-6:2010/A2:2021	Medical electrical equipment - Part 1-6: General Requirements for basic safety and essential performance -Collateral standard: usability
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 62366-1:2015/A1:2020	Medical devices -- Application of usability engineering to medical devices
EN ISO 17664-1:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices