EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 781235 R000

Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Address:
Mindray Building, Keji 12th Road South
Nanshan District,
High-tech Industrial Park
Shenzhen, Guangdong
518057
China

Single Registration Number: CN-MF-000014156

EU Authorised Representative: Shanghai International Holding Corp. GmbH (Europe)

Address:
Eiffestrasse 80
20537 Hamburg
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2024-01-26**

Current Issue Date: **2024-01-26**

Starting Validity Date: **2024-01-26**

Expiry Date: **2029-01-25**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

The Automated External Defibrillator is intended for semi-automated external defibrillation and automated external defibrillation. It also provides CPR feedback.

Risk Classification: Class III

Basic UDI-DI: 69449040AB010000423E

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Notes**
Automated External Defibrillator	BeneHeart C1/BeneHeart C1A BeneHeart C2/BeneHeart C2A BeneHeart S1/BeneHeart S1A BeneHeart S2/BeneHeart S2A BeneHeart C1 Fully Automatic BeneHeart C1A Fully Automatic BeneHeart C2 Fully Automatic BeneHeart C2A Fully Automatic BeneHeart S1 Fully Automatic BeneHeart S1A Fully Automatic BeneHeart S2 Fully Automatic BeneHeart S2A Fully Automatic	MDA 0305 MDA 0203 MDS 1010 MDS 1009	No differences in SW. The hardware difference is an addition of display for some categories. Other minor differences exist only in Front housing colours. BeneHeart C1/BeneHeart C1A, BeneHeart C2/BeneHeart C2A, BeneHeart S1/BeneHeart S1A, BeneHeart S2/BeneHeart S2A provides semi-automatic model, the others provide fully automatic model.

Product Codes: (Additional product codes, and their descriptions may be appended below)

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3792733	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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