



EU Technical Documentation Assessment Certificate

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

MDR 757846 R000

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

Address:

Mindray Building, Keji 12th Road South High-tech Industrial Park Nanshan District, 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: 2022-10-26 Starting Validity Date: 2022-11-22

Current Issue Date: **2022-11-22** Expiry Date: **2027-10-25**

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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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80 Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK. A Member of the BSI Group of Companies.





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Device Schedule:

Intended Purpose as per the Instructions for Use:

The Defibrillator/Monitor is intended for external defibrillation, internal defibrillation, synchronized cardioversion and semiautomated external defibrillation. It can also be used for non-invasive external pacing, CPR Feedback as well as ECG, Resp, SpO2, PR, NIBP, CO2, IBP and Temp monitoring.

Risk Classification: Class III

| Device Name | Model | Type (Codes as per (EU) 2017/2185) | Basic UDI-DI | Notes |
|----------------|----------------|---|----------------------|------------------------------------|
| Defibrillator | BeneHeart D5 | MDA 0305 | 69449040AB010000083E | The only difference is the shell |
| /Monitor | BeneHeart D6 | | | colour. |
| | BeneHeart D30 | | 69449040AB010000102Z | Minor differences exist only in |
| | BeneHeart D20 | | | screen size, layouts, and colours. |
| | BeneHeart D20A | | | |
| | BeneHeart D20C | | | No Temp and IBP. |
| | BeneHeart D60 | | 2 | Minor differences exist only in |
| | BeneHeart D50 | | 3, 11 | screen size, layouts, and colours. |
| | BeneHeart D50A | | 201 | |
| | BeneHeart D50C | | 2000 | |
| | BeneHeart DX | | | |
| | BeneHeart DM | | | Maria Maria |

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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 |
|------------|------------------|---|
| 2022-10-26 | 3538580 | Issued |
| Current | 3655180 | Supplemented – Addition of devices (BeneHeart D30 / |
| | | BeneHeart D20 / BeneHeart D20A / BeneHeart D20C / |
| | | BeneHeart D60 / BeneHeart D50 / BeneHeart D50A / |
| | | BeneHeart D50C / BeneHeart DX / BeneHeart DM) |

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