By Royal Charter

# 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**

Current Issue Date: **2022-11-22**

Starting Validity Date: **2022-11-22**

Expiry Date: **2027-10-25**

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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 semi-automated 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 /Monitor | BeneHeart D5 | MDA 0305 | 69449040AB010000083E | The only difference is the shell colour. |
| | BeneHeart D6 | | | |
| | BeneHeart D30 | | 69449040AB010000102Z | Minor differences exist only in screen size, layouts, and colours.<br><br>**No Temp and IBP.** |
| | BeneHeart D20 | | | |
| | BeneHeart D20A | | | |
| | BeneHeart D20C | | | |
| | BeneHeart D60 | | | Minor differences exist only in screen size, layouts, and colours. |
| | BeneHeart D50 | | | |
| | BeneHeart D50A | | | |
| | BeneHeart D50C | | | |
| | BeneHeart DX | | | |
| | BeneHeart DM | | | |

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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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