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. **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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