Test Report issued under the responsibility of:

TEST REPORT
IEC 60601-1
Medical Electrical Equipment
Part 1: General requirements for basic safety and essential performance

Report Number. ..... :	**GZES220500997501**
Date of issue ..... :	**2022-10-12**
Total number of pages ..... :	**288**
Name of Testing Laboratory preparing the Report ..... :	**SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch**
Applicant's name ..... :	**SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.**
Address ..... :	**Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen 518057, P.R. China**
Test specification:	
Standard ..... :	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
Test procedure ..... :	CB Scheme
Non-standard test method ..... :	N/A
TRF template used ..... :	IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No. ..... :	IEC60601_1U
Test Report Form(s) Originator .... :	UL(US)
Master TRF ..... :	2022-05-13

If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

This report is not valid as a CB Test Report unless signed by an approved IECEE Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

General disclaimer:

The test results presented in this report relate only to the object tested.
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Digitally signed by Alexa Gheorghe
Date: 2026.05.28 16:22:52 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Test item description ..... :	Defibrillator/Monitor		
Trade Mark(s) ..... :	mindray		
Manufacturer ..... :	Same as applicant		
Model/Type reference ..... :	BeneHeart D60, BeneHeart D50, BeneHeart D50A, BeneHeart D50C		
Ratings ..... :	AC 100-240 V, 50/60 Hz, 1.8 – 0.8 A DC 12-30.3 V, 15.5-6.5 A		
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):			
☒	**CB Testing Laboratory:**	SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch	
Testing location/ address.....:		No.198, Kezhu Road, Science City, Economic & Technological Development Area, Guangzhou, Guangdong, China	
Tested by (name, function, signature).....:		Tina Zhou Project Engineer	
Approved by (name, function, signature)...:		Gary Guo Project Reviewer	
☐	**Testing procedure: CTF Stage 1:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 2:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 3:**		
☐	**Testing procedure: CTF Stage 4:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
Supervised by (name, function, signature) :			

List of Attachments (including a total number of pages in each attachment):

Attachment 1: Photo documentation (from page 263 to page 278)

Attachment 2: System diagram of BeneHeart D60 (page 279)

Attachment 3: Accessories List (from page 280 to page 288)

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
Tests according to the following standards were carried out: **IEC 60601-1:2005 + A1:2012 + A2:2020** The submitted samples fulfilled the requirements of specified standards except the following clause was not evaluated in this test report: - Clause 11.7 Biocompatibility BeneHeart D60 with configuration of ECG, SpO_2, NIBP, CO_2, CPR, IBP, TEMP, external paddles and internal paddles, was selected to be subjected to full tests, BeneHeart D50A, BeneHeart D50, BeneHeart D50C was subjected to construction review.	No.198, Kezhu Road, Science City, Economic & Technological Development Area, Guangzhou, Guangdong, China

Summary of compliance with National Differences (List of countries addressed):

EU group difference:

☒ The product fulfils the requirements of EN 60601-1:2006 + A1:2013 + A2:2021 which is identical to IEC 60601-1:2005 + A1:2012 + A2: 2020, except for the following clause:

- Clause 11.7 Biocompatibility

Statement concerning the uncertainty of the measurement systems used for the tests

(may be required by the product standard or client)

☐ **Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:**

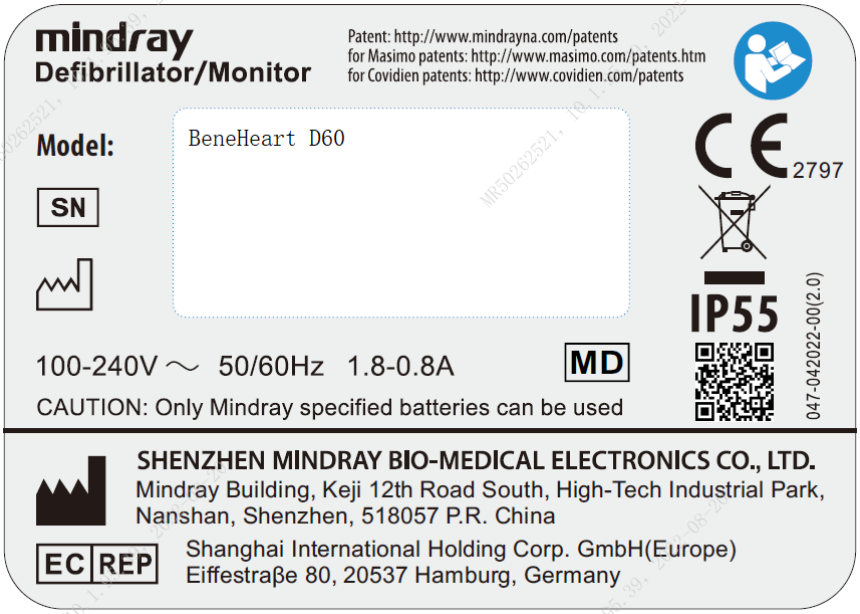
Procedure number, issue date and title:

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

☒ **Statement not required by the standard used for type testing**

Copy of marking plate:

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.



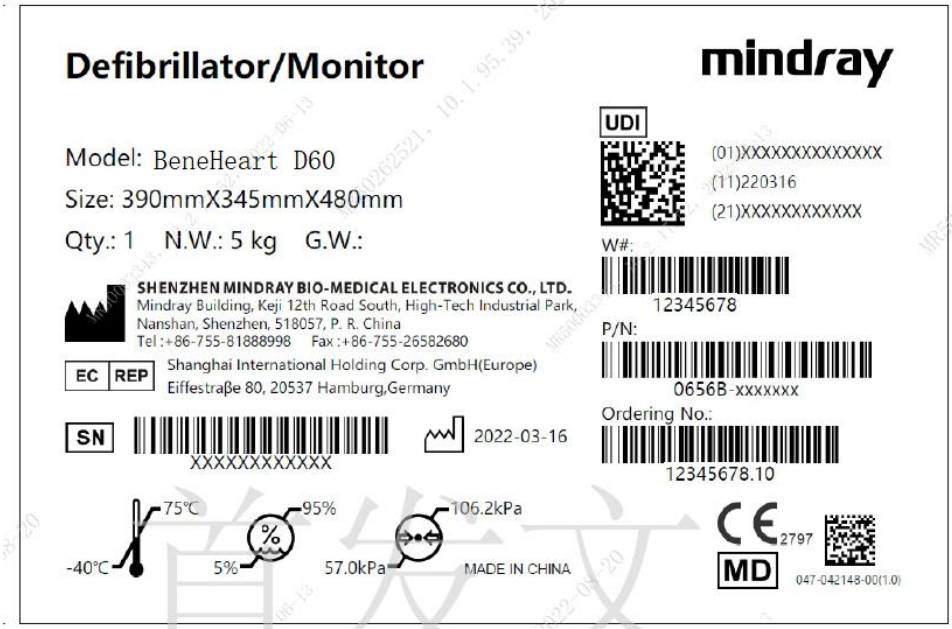
Main unit label template of BeneHeart D60(AC)

Main unit label template of BeneHeart D60(DC)

Applied part panel marking

The label of AC/DC adapter

Silk printing of Docking Station



The label of package

Test item particulars.....:	
Classification of installation and use.....:	Portable equipment with a fixed holder
Supply Connection.....:	internally powered / appliance coupler/power adapter/External DC power source
Device type (component/sub-assembly/ equipment/ system)……..:	System
Intended use (Including type of patient, application location)……:	See “General product information”
Mode of operation……:	Continuous
Accessories and detachable parts included……...:	See attachment 2
Other options include……...:	ECG, NIBP, SpO2, CO2, IBP, TEMP and CPR
Possible test case verdicts:	
- test case does not apply to the test object.....:	N/A
- test object does meet the requirement.....:	P (Pass)
- test object was not evaluated for the requirement……...:	N/E (collateral standards only)
- test object does not meet the requirement.....:	F (Fail)
Abbreviations used in the report	
- normal condition……: N.C.	- single fault condition .....: S.F.C.
- means of Operator protection ……: MOOP	- means of Patient protection ....: MOPP
Testing.....:	
Date of receipt of test item .....:	2022-05-30
Date (s) of performance of tests.....:	2022-05-30 to 2022-10-12
General remarks:	

"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested. This report shall not be reproduced except in full without the written approval of the testing laboratory.

List of test equipment must be kept on file and available for review. Additional test data and/or information provided in the attachments to this report.
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Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.
Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :	☐ **Yes** ☒ **Not applicable**

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies) ..... :	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. 1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen, P.R. China

General product information and other remarks:

Defibrillator/Monitors BeneHeart D60, BeneHeart D50, BeneHeart D50A, BeneHeart D50C (hereafter referred to as "the equipment") are intended for external defibrillation, internal defibrillation, synchronized cardioversion and semi-automatic defibrillation (AED). It can also be used for non-invasive external pacing, CPR feedback, CPR filter, ECG resting analysis as well as ECG, Resp, SpO2, PR, NIBP, IBP, Temp and CO2 monitoring.

The applied parts for external defibrillation and CO2 are defibrillation-proof type BF, while for ECG, SpO2, NIBP, IBP, TEMP, CPR and internal defibrillation are defibrillation-proof type CF.
The internal defibrillator electrodes are intended to be sterilized by moist heat (134ºC) method.

It can be used with CPR sensor (Manufacturer: mindray; Model: MR6401). The CPR sensor can be connected to the equipment forming an ME system to provide real-time CPR feedback, including the chest compression depth, rate and interruption time. For CPR sensor the report does the related test with CPR sensor, for itself safety report see KF-001R-3-0127 safety test report which shows CPR is in compliance with IEC/EN 60601-1.

The equipment is for use in hospital and pre-hospital settings by qualified medical personnel trained in the

operation of the equipment and qualified by training in basic life support, advanced cardiac life support or defibrillation. It is classified as frequent use defibrillator.
This equipment is intended for use during professional transport of a patient outside a healthcare facility.

The equipment is powered by appliance coupler connected to supply mains, and it can be internally powered with two types of internal rechargeable Li-ion battery, see appended Table 8.10 for details.
The degree of protection against ingress of water and particulate matter is IP55.

For SpO2, user can choose Mindray, MASIMO or NELLCOR. As the insulation of these SpO2 modules are the same.

This report includes four models for defibrillator/monitor, BeneHeart D60, BeneHeart D50A, BeneHeart D50, BeneHeart D50C, all models are identical except with different markings and color of front enclosure's appearance.

Difference description	BeneHeart D50	BeneHeart D50C	BeneHeart D50A	BeneHeart D60
Color	Grey	Blue	Blue	Grey
Power supply	AC power supply, Docking station(DC), Docking station(AC), AC/DC adapter	AC power supply, Docking station(DC), Docking station(AC), AC/DC adapter	AC power supply, Docking station(DC), Docking station(AC), AC/DC adapter	AC power supply, Docking station(DC), Docking station(AC), AC/DC adapter

Software version: V01

Operating Environment: -20~55ºC for ECG and Manual defibrillation, 0~50ºC for other functions. 5% to 95% R.H. 57.0~106.2 kPa.

Attachment 1: Photo documentation

Details of: BeneHeart D60

View:

[☒] general

[☒] front

[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom

Details of: BeneHeart D60

View:

[☒] general

[ ] front

[☒] rear

[ ] right

[ ] left

[ ] top

[ ] bottom

Attachment 1: Photo documentation

Details of: Transport dock

View:

[☒] general

[ ] front

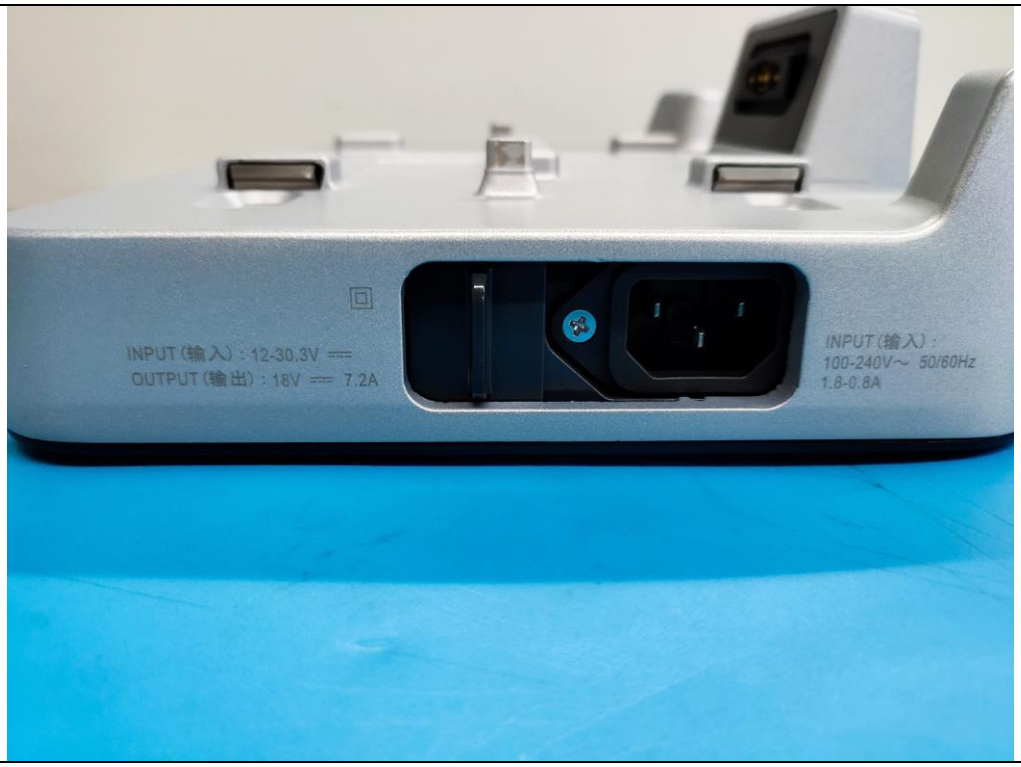
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Details of: Transport dock

View:

[☒] general

[ ] front

[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom