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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 109546 0015 Rev. 00

Manufacturer:

Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.
No.1 Baisheng Road Development Zone
212300 Danyang, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000012834

Authorized Representative:

Metrax GmbH
Rheinwaldstr. 22, 78628 Rottweil, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment.
The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result. Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 109546 0015 Rev. 00

Report No.: 0713330781

Valid from: 2025-02-28
Valid until: 2030-02-27

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-02-28

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No. G70 109546 0015 Rev. 00

Classification:	Class III
Basic UDI-DI:	6933257929609AR
Intended Purpose:	HeartSave Y|YA devices are designed to be used in case of suspected sudden cardiac arrest, to guide the operator to start resuscitation, to analyze victim's ECG, to deliver defibrillation therapy through self-adhesive electrodes in case of a shockable rhythm and to guide the operator to perform cardiopulmonary resuscitation.
Device(s):	Automated External Defibrillator HeartSave Y0 HeartSave Y1 HeartSave Y2 HeartSave Y3 HeartSave Y5 HeartSave Y6 HeartSave Y7 HeartSave Y8

Classification:	Class III
Basic UDI-DI:	6933257929685B9
Intended Purpose:	HeartSave Y|YA devices are designed to be used in case of suspected sudden cardiac arrest, to guide the operator to start resuscitation, to analyze victim's ECG, to deliver defibrillation therapy through self-adhesive electrodes in case of a shockable rhythm and to guide the operator to perform cardiopulmonary resuscitation.
Device(s):	Automated External Defibrillator HeartSave YA0 HeartSave YA1 HeartSave YA2 HeartSave YA3 HeartSave YA5 HeartSave YA6 HeartSave YA7 HeartSave YA8

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The validity of this certificate depends on conditions and/or is limited to the following: ./.

Revision History:

Rev.	Dated	Report	Description
00	2025-02-28	0713330781	- Amended: Other

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