ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 107512 0004 Rev. 02

**Manufacturer:**

**ViVest Medical Technology Co., Ltd.**
Unit 401,501, Building No.2, Zone B
SIP Biobay Phase 5, No.21
Dongyanli Road, Suzhou Industrial Park
215123 Suzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000015304

**Authorized Representative:**

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, 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 chapter I 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 107512 0004 Rev. 02

**Report No.:** 713387876

**Preceding Certificate No.:** G70 107512 0004 Rev. 01

**Valid from:** 2026-04-10
**Valid until:** 2029-11-21

**Date of Initial Issuance:** 2024-11-22

Christoph Dicks
Head of Certification/Notified Body

**Issue date:** 2026-03-26


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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## No. G70 107512 0004 Rev. 02

| | |
|---|---|
| **Classification:** | Class III |
| **Basic UDI-DI:** | 697310724PB01ET |
| **Intended Purpose:** | Automated External Defibrillator (AED) is indicated for use on patients with suspected Sudden Cardiac Arrest (SCA) who are unconscious, unresponsive and not breathing or breathing abnormally. |
| **Device(s):** | Automated External Defibrillator<br>Models:<br>- A1<br>- A3 |

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| | |
|---|---|
| **The validity of this certificate depends on conditions and/or is limited to the following:** | N/A |

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2024-11-22 | 713329781 | Initial issuance |
| 01 | 2025-11-21 | 713378394 | Amended: Other<br>Amended: Change of certificate holder's data |
| 02 | 2026-04-10 | 713387876 | Supplemented: Change to the approved type(s)/device(s) |


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