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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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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 079546 0031 Rev. 00

**Manufacturer:**

**ZOLL Medical Corporation**
269 Mill Road
Chelmsford MA 01824-4105
USA

SRN Manufacturer - US-MF-000021386

**Authorized Representative:**

ZOLL International Holding B.V.
Einsteinweg 8A, 6662 PW Elst, THE NETHERLANDS

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 079546 0031 Rev. 00

**Report No.:** 72169351

**Valid from:** 2024-09-19
**Valid until:** 2029-09-18

Christoph Dicks
Head of Certification/Notified Body

**Issue date:** 2024-09-19


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| | |
|---|---|
| **Classification:** | Class III |
| **Device Group:** | Z12030501 - SEMI-AUTOMATIC DEFIBRILLATORS |
| **Basic UDI-DI:** | 08479460RTF |
| **Intended Purpose:** | The intended purpose of the ZOLL AED Plus is to help victims of sudden cardiac arrest. Using compatible ZOLL defibrillation electrodes which connect the patient to the ZOLL AED Plus, the AED automatically analyzes the victim's ECG rhythm to determine whether an electrical shock should be delivered. If the AED detects a shockable rhythm (coarse ventricular fibrillation or wide complex ventricular tachycardia), it alerts the rescuer that a shock is advised and then it either issues instructions to press the flashing shock button (semi-automatic model) or it automatically delivers the shock after a 3 second countdown (fully automatic model). The AED then prompts the rescuer to perform CPR for a pre-configured period of time. |
| **Device(s):** | AED Plus<br>AED Plus Aviation |

| | |
|---|---|
| **Classification:** | Class III |
| **Device Group:** | Z12030503 - AUTOMATIC DEFIBRILLATORS |
| **Basic UDI-DI:** | 08479460RTF |
| **Intended Purpose:** | The intended purpose of the ZOLL AED Plus is to help victims of sudden cardiac arrest. Using compatible ZOLL defibrillation electrodes which connect the patient to the ZOLL AED Plus, the AED automatically analyzes the victim's ECG rhythm to determine whether an electrical shock should be delivered. If the AED detects a shockable rhythm (coarse ventricular fibrillation or wide complex ventricular tachycardia), it alerts the rescuer that a shock is advised and then it either issues instructions to press the flashing shock button (semi-automatic model) or it automatically delivers the shock after a 3 second countdown (fully automatic model). The AED then prompts the rescuer to perform CPR for a pre-configured period of time. |
| **Device(s):** | AED Plus Fully Automatic |

AED Plus
AED Plus Aviation
AED Plus Fully Automatic


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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 | 2024-09-19 | 72169351 | Initial issuance<br>Amended: Other |



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