



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 079546 0030 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 and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:G70_079546_0030_Rev.00

Report No.: 72169555

Valid from: 2024-02-02

Valid until: 2029-02-01

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-02-02



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 0030 Rev. 00

Classification: Class III
Device Group: Z12030503 - AUTOMATIC DEFIBRILLATORS
Basic UDI-DI: 08479460DSK
Intended Purpose: The intended purpose of the ZOLL AED 3 is to help victims of sudden cardiac arrest. Using compatible ZOLL defibrillation electrodes which connect the patient to the ZOLL AED 3, 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): ZOLL AED 3 (Automatic & Aviation Automatic) Variants:
 ZOLL AED 3 (Automatic)
 ZOLL AED 3 (Aviation Automatic)

Classification: Class III
Device Group: Z12030501 - SEMI-AUTOMATIC DEFIBRILLATORS
Basic UDI-DI: 08479460DSK
Intended Purpose: The intended purpose of the ZOLL AED 3 is to help victims of sudden cardiac arrest. Using compatible ZOLL defibrillation electrodes which connect the patient to the ZOLL AED 3, 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): ZOLL AED 3 (Semi-Automatic & Aviation Semi-Automatic) Variants:
 ZOLL AED 3 (Semi-Automatic)
 ZOLL AED 3 (BLS)
 ZOLL AED 3 (Aviation Semi-Automatic)
 ZOLL AED 3 (Aviation BLS)



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 0030 Rev. 00

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

Revision History:

Rev.	Dated	Report	Description
00	2024-02-02	72169555	Initial issuance