

### Specificație tehnică completată

**Model: AED Plus, Producător: ZOLL Medical, Tara: SUA**

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină completată de către autoritatea ofertantă
<p>Defibrilator extern, automat Cod 130410 Descriere Defibrilator automat cu analiză ECG, încarcă automat. Defibrilatoarele externe automate se utilizează în secțiile de medicină urgentă sau de către poliție și pompieri – personalul care este responsabil pentru urgențe medicale. De asemenea poate fi utilizat și de oamenii de rând în hol, secția de internare. Parametrul Specificația Defibrilator Tip automat Ghidare vocală în română sau rusă da Energia maximală de descărcare <math>\geq 300</math> J Categorie de pacient: Adult și Pediatric da Secvențe de energie repartizate conform categoriei de pacient: Adult și Pediatric da Detectare automată a tipului de pacient: Adult și Pediatric da</p> <p>Forma de undă la ieșire bifazică</p> <p>Indicație de resuscitare cardio-respiratorie (CPR) da Ritmul pentru resuscitarea cardio-respiratorie (CPR) da Indicatori vizuali și auditivi Ton a ritmului cardiac da Erori tehnice da Starea tehnică de funcționare a dispozitivului da Analiza semnalului ECG Automată da Timpul de analiză <math>&lt; 15</math> s Autotestare zilnică, săptămânal, lunar da Indicator statut dispozitiv fara al scoate din dulap da Timp de încărcare a energiei maxime de defibrilare <math>&lt; 10</math> s Baterie Fără posibilitatea de reîncărcare. Timpul de funcționare și așteptare <math>\geq 5</math> ani, după care bateria poate fi înlocuită da Indicație pentru necesitatea de a înlocui bateria da Timp de operare <math>\geq 300</math> de descărcări la energia maximă Greutate <math>\leq 3</math> kg Accesorii Electrozi de defibrilare AED de unică utilizare Adult, unică utilizare, cu termenul de valabilitate 2 ani la momentul livrării <math>\geq 2</math> set. Pediatrice cu autoidentificare, unică utilizare, cu termenul de valabilitate 2 ani la momentul livrării <math>\geq 2</math> set.</p>	<p>Defibrilator extern, automat <b>DA</b> Cod 130410 Descriere Defibrilator automat cu analiză ECG, încarcă automat. Defibrilatoarele externe automate se utilizează în secțiile de medicină urgentă sau de către poliție și pompieri – personalul care este responsabil pentru urgențe medicale. De asemenea poate fi utilizat și de oamenii de rând în hol, secția de internare.<b>DA</b> Parametrul Specificația Defibrilator Tip automat <b>DA</b> Ghidare vocală în rusă <b>DA</b> Energia maximală de – <b>200 J DA</b> Categorie de pacient: Adult și Pediatric <b>DA</b> Secvențe de energie repartizate conform categoriei de pacient: Adult și Pediatric <b>DA</b> Detectare automată a tipului de pacient: Adult și Pediatric <b>DA o data cu conectare electrozilor corespunzatori</b> Forma de undă la ieșire <b>bifazică rectiliniu avind un radament energetic mai eficient de cit cel bifazic calsic.DA</b></p> <p>Indicație de resuscitare cardio-respiratorie (CPR) <b>DA</b> Ritmul pentru resuscitarea cardio-respiratorie (CPR) <b>DA</b> Indicatori vizuali și auditivi Ton a ritmului cardiac <b>DA</b> Erori tehnice <b>DA</b> Starea tehnică de funcționare a dispozitivului <b>DA</b> Analiza semnalului ECG Automată <b>DA</b> Timpul de analiză <math>&lt; 15</math> s <b>DA</b> Autotestare zilnică, săptămânal, lunar da Indicator statut dispozitiv fara al scoate din dulap <b>Da</b> Timp de încărcare a energiei maxime de defibrilare <math>&lt; 10</math> s <b>DA</b> Baterie Fără posibilitatea de reîncărcare. Timpul de funcționare și așteptare <math>\geq 5</math> ani, după care bateria poate fi înlocuită <b>DA</b> Indicație pentru necesitatea de a înlocui bateria da Timp de operare 225 de descărcări la energia maximă <b>DA</b> Greutate - <b>3.1 kg Da</b> Accesorii Electrozi de defibrilare AED de unică utilizare Adult, unică utilizare, cu termenul de valabilitate <b>5 ani</b> la momentul livrării - 2 set. <b>DA</b> Pediatrice cu autoidentificare, unică utilizare, cu termenul de valabilitate 2 ani la momentul livrării - 2 set. <b>DA</b></p>

<p>Boxă de urgență instalată pe perete pentru depozitarea dispozitivului Boxă de urgență da</p> <p>Ușă frontală transparentă dotat cu mâner da</p> <p>Simbolul international și inscripția AED pe cutie da</p>	<p>Boxă de urgență instalată pe perete pentru depozitarea dispozitivului Boxă de urgență <b>DA</b></p> <p>Ușă frontală transparentă dotat cu mâner <b>DA</b></p> <p>Simbolul international și inscripția AED pe cutie <b>DA</b></p>
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**AED Plus®**

**ZOLL®**



**NOT ALL AEDS  
ARE CREATED EQUAL**



# ARE YOU PREPARED TO HELP IN A HEARTBEAT?

It happens in a split second. A person collapses — the victim of sudden cardiac arrest (SCA) — and the clock starts ticking. You call for help, and medical personnel are on their way. But precious seconds are racing by. The victim's best chance for survival is immediate CPR and a rescuer with an automated external defibrillator (AED).

CPR plus early defibrillation can more than double the rate of survival from out-of-hospital cardiac arrest.

– 2015 AHA Guidelines<sup>1</sup>

## Designed for Unexpected Heroes™

The latest guidelines from resuscitation councils worldwide are clear: Successful defibrillation must be supported with high-quality CPR. The AED's first heart analysis is critical. If it calls for no shock, only CPR can lead to a shockable rhythm on the next analysis. CPR provides a struggling heart with oxygenated blood needed to help restore a normal rhythm.

The ZOLL AED Plus® defibrillator will guide you through the process of performing high-quality CPR and will, if needed, deliver a potentially lifesaving shock to the heart. With a ZOLL AED Plus and quick action, you could help avert tragedy.

"...monitoring of CPR quality is arguably one of the most significant advances in resuscitation practice in the past 20 years and one that should be incorporated into every resuscitation and every professional rescuer program."

– American Heart Association CPR Quality Consensus Statement<sup>2</sup>





# EMPOWERING RESCUERS WITH REAL CPR HELP®

While only 50% of sudden cardiac arrest victims will initially need a shock, nearly all will require CPR to increase the flow of oxygenated blood to the heart and brain.

ZOLL's proprietary Real CPR Help® technology helps guide rescuers to perform CPR in accordance with the most recent guidelines for depth and rate of compressions. You will know when you are delivering high-quality CPR. The user-friendly and intuitive design of the ZOLL AED Plus will help give unexpected heroes the confidence and knowledge they need to treat SCA.



SHOCKS: 01 00:20  
GOOD  
COMPRESSIONS

SHOCKS: 01 00:22  
PUSH  
HARDER

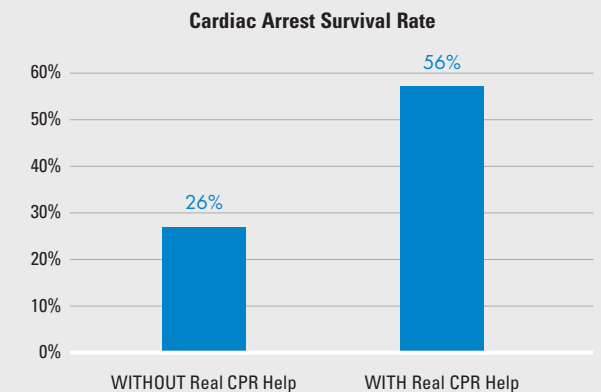
SHOCKS: 00 00:38  
DON'T TOUCH  
PATIENT  
ANALYZING

Integrated, real-time feedback provides visual and audio prompts to "Push Harder" or confirms when you are doing "Good Compressions," keeping you on track to administer potentially life-saving CPR.

## Survival More than Doubled

In a large study conducted with EMS providers in Arizona, ZOLL technology and training combined to more than double survival to discharge from the hospital for patients who suffered cardiac arrest.<sup>3</sup> This study used professional defibrillators equipped with the same Real CPR Help technology found in the AED Plus.

Half of the victims were treated with Real CPR Help turned on while the other half were treated with this technology turned off. The study found that using Real CPR Help more than doubled survival when the individual's collapse was witnessed by someone and the irregular heart rhythm was ventricular fibrillation.







# EXCEPTIONAL SUPPORT WHEN YOU NEED IT MOST

## SMART

### Rescue with confidence

In addition to step-by-step audio prompts, our proven Real CPR Help technology includes a compression depth indicator that provides real-time visual guidance to help you deliver the best possible CPR.

### Simple, accurate pad placement

Speed is of the essence when treating a cardiac arrest victim. ZOLL's CPR-D-padz® electrodes feature a unique one-piece design to ensure easy and accurate placement. Electrodes come with a rescue accessory kit that includes scissors, gloves, a mask, and other items.

## READY

### Ready for the rescue

Industry-leading batteries and pads that last five years mean fewer replacements, less maintenance, and an AED that's ready when needed.

### Smart investment

Once installed, the AED Plus has the lowest total cost of ownership compared to other AEDs. It's an invaluable investment that can help save a life.

### Designed for durability

Designed to withstand harsh environments and temperature extremes, the AED Plus has an ingress protection (IP) rating of IP55, which means it is highly resistant to dust and moisture.

## AED Program Management

Maximize the benefits of your ZOLL AED

### Is Your AED Ready?

Your AED needs to be ready the day you need it, not just the day you buy it. AED program management software can help you track and document AED inspections as well as pad and battery expirations.

### Are Your Trained Responders Ready?

AEDs are most effective when used by rescuers who know how to use them. Easily track and manage your trained responders and the status of their AED/CPR certifications with an AED program management solution.

### Do You Have a Plan in Place?

Having a plan for what to do before, during, and after an event pays off. A program management system can help you document all of these steps before an emergency happens.

### Is Your Program Compliant?

Tracking consumables' expirations, managing your responder certifications, and maintaining written response protocols are required in many states. Utilize AED program management to keep track of your obligation and compliance with local regulations.

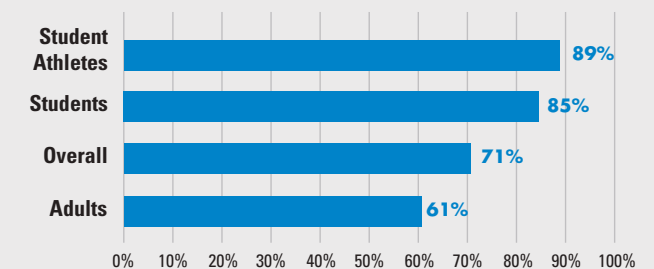
Studies have shown that well-implemented AED programs can significantly improve survival rates.<sup>4</sup>

## AED Programs Pay Off

Research based on data collected from more than 2,000 U.S. high schools has shown that schools with AED programs experience an overall survival rate of 71%.<sup>4</sup>

The authors concluded that "High school AED programs demonstrate a high survival rate for students and adults who suffer sudden cardiac arrest on school campus. School-based AED programs are strongly encouraged."

Survival Rates for 2,045 U.S. High Schools  
over a Two-year Period





## Be prepared with a ZOLL AED as your rescue partner.

### Every sudden cardiac arrest victim will need high-quality CPR

- The AED Plus with Real CPR Help will give you integrated, real-time feedback to help you deliver the best possible CPR

### Time is of the essence

- One-piece electrode design makes applying pads simple, fast, and accurate

### Invest in the ability to help save a life

- A low total cost of ownership and batteries and pads that last five years mean you will be ready to help in a heartbeat

<sup>1</sup>AHA 2015 Guidelines: pg. S402

<sup>2</sup>AHA CPR Quality Consensus Statement. *Circulation*. 2013;128: pg. 420

<sup>3</sup>Bobrow BJ, et al. *Ann Emerg Med*. 2013 Jul;62(1):47-56.e1.

<sup>4</sup>Drezner JA, et al. *Br J Sports Med*. 2013;47:1179-1183.

## ZOLL MEDICAL CORPORATION

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For subsidiary addresses and fax numbers, as well as other global locations, please go to [www.zoll.com/contacts](http://www.zoll.com/contacts).

# ZOLL®

# AED Plus®

## Technical Specifications



### More than CPR. This Is Real CPR Help®.

Only half of sudden cardiac arrest victims will initially need a shock, but nearly all require high-quality CPR. ZOLL® offers the only AEDs that support rescuers with integrated text, voice, and visual prompts — Real CPR Help®. Its real-time feedback on compression rate and depth helps rescuers administer high-quality CPR.

### Smart Investment with a Low Total Cost of Ownership

Longer-lasting batteries and pads require fewer replacement parts, adding up to considerable cost savings over time and rescue readiness in a cardiac arrest emergency.

### Intuitive One-piece Electrode Pad Design

Speed is of the essence when treating a victim of sudden cardiac arrest. ZOLL's CPR-D-padz® electrodes feature a unique one-piece, pull-strip design to ensure fast and accurate placement and to minimize the potential of pads being dropped or stuck together.

### Designed to be Durable

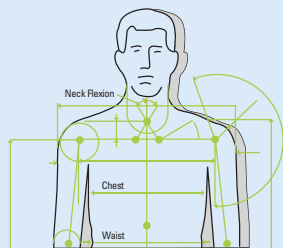
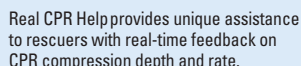
AEDs are often subjected to rough handling and extreme conditions during an emergency. The ZOLL AED Plus® is highly resistant to dust and moisture and has an ingress protection (IP) rating of 55, among the highest in the industry. It also meets IEC 60601-1-2; 100G for shock and military (MIL Standard 883C).

### Options to Meet Your Preferred Shock Protocol

The ZOLL AED Plus is available in both semi-automatic (shock button manually pressed by rescuer if a shockable rhythm is detected) or fully automatic (AED automatically administers a shock if a shockable rhythm is detected).

# ZOLL®





ZOLL's one-piece CPR-D-padz electrodes are designed to fit 99% of the population's chest anatomy.



CPR-D-padz offer clear anatomical placement illustrations and a CPR hand positioning landmark.



CPR-D-padz come complete with rescue essentials, including a barrier mask, a razor, scissors, disposable gloves, and a towelette.

ZOLL

**AED Plus®**  
Accessories and Training Products

**ZOLL®**



**ACCESSORIES FOR EVERY RESCUE**





#### 7-inch Standard Wall Cabinet

7-inch alarmed wall cabinet holds AED Plus® (without carry case) and one spare set of electrodes  
Part# 8000-0817

## WALL CABINETRY

Solutions to protect your AED and improve visibility



#### Semirecessed Wall Cabinet

- Alarmed AED wall cabinet holds AED Plus (without carry case) and one spare set of electrodes
- Meets ADA (American Disability Act) guidelines
- Professional installation recommended

Part# 8000-0814



#### Fully Recessed Wall Cabinet

- Alarmed AED wall cabinet holds AED Plus (without carry case) and one spare set of electrodes
- Meets building code guidelines that prohibit cabinet from protruding more than 2 inches from wall
- Meets ADA (American Disability Act) guidelines
- Professional installation recommended

Part# 8000-0811



#### 9-inch Standard Wall Cabinet

- 9-inch alarmed wall cabinet accommodates AED Plus in carry case with one spare set of electrodes

Part# 8000-0855

# ELECTRODES, BATTERIES & ACCESSORY KIT

Everything you need to keep your AED Plus ready to use



## CPR-D-padz® Electrodes

- One-piece design ensures fast and accurate placement
- For use on adult patients and children over the age of 8 or > 55 pounds (25 kilograms)
- Built into the electrodes, Real CPR Help® technology senses the rate and depth of chest compressions
- Five-year shelf life

**Part # 8900-0800-01**



## Pedi-padz® II Pediatric Electrodes

- ZOLL's intelligent pediatric capability is built into the AED Plus. The AED can sense when Pedi-padz II are being used and will switch the AED Plus from adult to pediatric mode, modifying the device so it will provide an appropriate pediatric ECG analysis algorithm and therapy energy level.
- For use with patients under the age of 8 years or < 55 pounds (25 kilograms)
- Two-year shelf life

*Caution: Pediatric electrodes should never be used with an adult patient*

**Part # 8900-0810-01**



## Accessory Kit

- The AED Plus accessory kit includes scissors, disposable razor, face barrier/shield, antimicrobial wipe, and dry towel.

*Note: This kit is included and attached to every set of ZOLL CPR-D-padz® electrodes.*

**Part # 8900-0807-01**



## Type 123 Lithium Batteries (sleeve of 10)

- Nonproprietary off-the-shelf Duracell 123 lithium batteries
- 10-year shelf life
- 5-year standby life once installed in the AED Plus

*Caution: Only use batteries from a ZOLL-approved manufacturer (refer to User Manual).*

**Part # 8000-0807-01**



# MOUNTING BRACKET & SIGNAGE

Ensure AED visibility



## Mounting Bracket

- Bracket is used to mount AED Plus on wall without carry case

Part# 8000-0809-01



## AED Wall Decal

- 4" x 4" AED decal suitable for indoor or outdoor use

Part# 8000-0849-01



## AED Sign Package

- 3D wall sign and 8.5" x 11" wall-mounted sign to improve AED visibility

Part# 8000-0825

# CARRY CASES & BAGS

Options for storage and transport



## Large Pelican Case

- Protection for AED Plus in more demanding environments
- Large enough to store AED Plus, CPR-D-padz, Pedi-padz II, and sleeve of 10 batteries
- Dimensions: 19" x 15.4" x 7.6" (48.3 cm x 39.1 cm x 19.3 cm)
- IP67 certified
- Military Standard C-4150J

Part# 8000-0837-01



## Small Pelican Case

- Protection for AED Plus in more demanding environments
- Stores AED Plus unit only
- Dimensions: 16" x 13" x 6.9" (40.6 cm x 33 cm x 17.5 cm)

Part# 8000-0836-01



## Soft Carry Bag

- Provides easy access and quick retrieval of the AED Plus and spare accessories
- Pockets for storing extra electrodes and batteries

Part# 8000-0802-01



## AED DEVICE MANAGEMENT & UPGRADE TOOLS

### RescueNet® Code Review Software

- Software providing ECG, vital sign data, and rate and depth of compressions for complete rescue review
- Can be downloaded at no cost directly from ZOLL website

**Part# 8000-0608-01**

### Administrative Software (ZAS)

- Software to reconfigure settings on ZOLL AED Plus
- Requires use of infrared IrDA adapter (sold separately)
- Software can be downloaded at no cost directly from ZOLL website

**Part# 8000-0311-01**

### AHA Guidelines Upgrade Kit

- Kit upgrading ZOLL devices manufactured prior to 2010 to current AHA Guidelines
- Includes Administrative Software (ZAS) CD, instructions, and labels to upgrade AED Plus faceplate
- Requires use of IrDA adapter (sold separately)

**Part# 7771-000011-01**

### USB-to-IrDA Adapter Kit

- USB-to-IrDA adapter cable and driver software
- Required for AED Plus configuration and post-rescue event data review

**Part# 8000-0815**

### Mini USB-to-IrDA Adapter Kit

- Mini USB-to-IrDA adapter cable and driver software
- Required for AED Plus configuration and post-rescue event data review

**Part# 8000-1200**

### RS232-to-IrDA Adapter Kit

- RS232-to IrDA adapter cable and driver software
- Required for AED Plus configuration and post-rescue event data review

**Part# 8000-0816**



# AED PLUS CLINICAL UNIT TRAINING DEVICES & ACCESSORIES



## AED Plus Demo Kit

- Kit to demonstrate Real CPR Help® with clinical AED Plus
- Includes CPR-D Demo electrodes and manikin in large carry bag
- Clinical AED Plus and simulator not included

Part # 8000-0834-01



## CPR-D Demo Electrodes

- Demonstration electrode pads for use with clinical AED Plus
- Requires simulator

Part # 8900-5007



## Demo Manikin

- Adult manikin for AED/CPR training
- Use with AED Plus clinical unit and AED Plus Trainer2
- Training pads and simulator sold separately

Part # 8000-0835-01



## AED Plus Simulator

- Simulates heart rhythm for AED Plus demonstration using clinical unit

Part # 8000-0819-01



## Travel Trainer

- One-piece, compact, easy-to-carry demonstration tool for clinical AED Plus
- Simulates VF and normal heart rhythms

Part # 8008-0006-01

# AED PLUS TRAINER2 & ACCESSORIES

Everything you need to simulate a rescue with your AED Plus Trainer2



## AED Plus Trainer2

- Allows the student to experience what it's like to help save a life with the AED Plus. Choose from four different training scenarios or have complete manual control of the entire rescue. A wireless remote lets you control multiple Trainer II devices.
- Ships with Operator's Manual, batteries, wireless remote, and adult training electrodes
- Replacement adult training electrodes, pediatric training electrodes, and replacement adhesive gel can be purchased separately as needed

Part # 8008-0050-01 (semiautomatic)

Part# 8008-000052-01 (automatic)



## Pedi-padz II Training Electrodes

- Pediatric electrodes for use with the Trainer2

Part # 8900-000861-01  
(pack of 6)



## Replacement Trainer II Wireless Remote

- Wireless remote for use with the Trainer2

Part # 8008-0007



## Replacement Adhesive Gel for CPR-D-padz Training Electrodes

- Gel must be applied to the reusable pad before use.

Part # 8900-0803-01 (pack of 5)



## AED Plus Trainer2 Soft Carry Case

- Clearly identifies the device as a training unit and provides a convenient way to transport the Trainer2. Includes a pocket for accessories.

Part # 8000-0375-01



## Demo Manikin

- Adult manikin for AED/CPR training use with AED Plus clinical unit and AED Plus Trainer2
- Training pads and simulator sold separately

Part # 8000-0835-01



## CPR-D-padz Training Electrodes

- Adult electrodes for use with the Trainer2. Replacement gel can be purchased separately.

Part # 8900-0804-01





# AED PROGRAM MANAGEMENT

Stay prepared to save a life

## PlusTrac Professional AED Program Management for a single AED

- Medical Authorization/Rx
- Online management software access
- Protocol and EMS templates
- AED Law library and support knowledge base
- Email reminders and alert notifications
- Complete customer support/implementation
- Post-event services and loaner program

**1 Year**

**Part# 8000-1110-01**

**5 Year**

**Part# 8000-1111-01**

## PlusTrac Essentials AED Program Management for a single AED

- Medical Authorization/Rx
- Online management software access
- Protocol and EMS templates
- AED Law library and support knowledge base
- Email reminders and alert notifications

**1 Year**

**Part# 8000-1116-01**

**5 Year**

**Part# 8000-1117-01**

For general product-related questions or assistance with where to buy ZOLL accessories, contact Customer Support at 800 348-9011. For technical questions about your ZOLL AED Plus or accessories, contact Technical Support at 978 421-9460.

## ZOLL MEDICAL CORPORATION

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## DECLARATION OF CONFORMITY



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



**ZOLL International Holding B.V.**  
Newtonweg 18  
6662 PV ELST  
The Netherlands

**Product:** ZOLL AED Plus®  
ZOLL AED Plus® Fully Automatic  
See Attached Catalog List

ZOLL declares that the above products conform to European Council Directive 93/42/EEC (Medical Device Directive) Class IIb per rule 9 of Annex IX, assessed per Annex II.

This declaration applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.

The quality system under which these products were designed and manufactured has been found to be in compliance with the Medical Device Directive including European Standard EN ISO 13485:2016 certified by the Notified Body TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany (Notified Body Number 0123).

The above products were in conformance with the provisions of Council Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment which was repealed by Directive 2012/19/EU of the European parliament and of the council of 4 July 2012 on waste electrical and electronic equipment (WEEE). At this time the above products are in conformance with the provisions of Directive 2012/19/EU of the European parliament and of the council of 4 July 2012 on waste electrical and electronic equipment (WEEE).

The above products are in conformance with the provisions of Council Directive 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment which apply to them.

3/4/2021

\_\_\_\_\_  
Name: Elizabeth McMeniman  
Position: Director, Regulatory Affairs  
Location: Chelmsford, MA USA

\_\_\_\_\_  
Date

Catalog Number	Description
20000000100011020	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, 50HZ, FRENCH
20000000100011100	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, 50HZ, SPANISH
20000000300011070	MAIN ASSY, PS SERIES, NO GRAPHICS, LCD, NO VOICE RCDG, 50HZ, UK (PROPER)
20100000101011020	AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RCDG, 50HZ, FRENCH, AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RECORDING, 50HZ, FRENCH
20100000101011050	AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RCDG, 50HZ, UK
20100000101011080	AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RCDG, 50HZ, GERMAN, AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RECORDING, 50HZ, GERMAN, ZOLL AED Plus, "Public Safety" Serie, mit graphischem Cover
20100000101011100	AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RCDG, ERC, SPANISH, AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RECORDING, 50HZ, SPANISH
20100000101011110	AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RCDG, 50HZ, ITALIAN, AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RECORDING, 50HZ, ITALIAN
20100000101011160	AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RECORDING, 50HZ, DUTCH, ZOLL AED Plus, PS Serie, grafische deksel, zonder stemopname optie
20100000101011180	AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RCDG, 50HZ, PORTUGUESE
20100000101011210	AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RCDG, 50HZ, FINNISH
20100000101011280	AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RCDG, INTERNATIONAL AHA ENGLISH
20100000102011010	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, ENGLISH
20100000102011020	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, FRENCH, AED Plus, Semi- Automatique, Interface avec pictogramme, FR, Défibrillateur ZOLL AED Plus semi- automatique - interface pictogrammes, ZOLL "Public Safety" Serie AED Plus, französisch
20100000102011050	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, UK, ZOLL AED Plus, PS Serie, zonder stemopname optie, Engels, ZOLL AED Plus, PS Series, English, ZOLL AED PLUS, PS SERIES, LCD, NO VOICE RCDG, UK
20100000102011070	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, UK (PROPER)
20100000102011080	AED Plus senza Registrazione Audio Ambientale e con coperchio AED in lingua tedesca, AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, GERMAN, ZOLL "Public Safety" Serie AED Plus, ZOLL AED Plus, PS Serie, zonder stemopname optie, Duits
20100000102011090	AED PLUS, PS SERIES, W/AED CVR. LCD, NO VOICE RCDG, AHA, SWITZERLAND/GERMAN
20100000102011100	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, ERC, SPANISH, ZOLL AED PLUS, PS SERIES, LCD, NO VOICE RECORDING, SPANISH
20100000102011110	AED Plus senza Registrazione Audio Ambientale e con coperchio AED, AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, ITALIAN, ZOLL AED PLUS, PS SERIES, LCD, NO VOICE RECORDING, ITALIAN
20100000102011160	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, DUTCH, ZOLL AED Plus, PS Serie, zonder stemopname optie, Nederlands, ZOLL AED PLUS, PS SERIES, LCD, NO VOICE RECORDING, NETHERLANDS
20100000102011180	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, PORTUGUESE, ZOLL AED PLUS, PS SERIES, LCD, NO VOICE RECORDING, PORTUGUESE
20100000102011210	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, 50HZ, FINNISH
20100000102011280	AED PLUS, PS SERIES, LCD, NO VOICE RCDG, INTERNATIONAL AHA ENGLISH, AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, INTERNATIONAL AHA ENGLISH
20100000102011410	AED Plus con coperchio AED, no reg. audio. Linee guida AHA, AED PLUS, PS SERIES, LCD, NO VOICE RCDG, AHA, SWITZERLAND/ITALIAN
20100000102011550	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, TURK



Catalog Number	Description
20100000302011050	AED PLUS, PS SERIES NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, UK, AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, UK
20100000302011070	AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, UK (PROPER)
20100001101011100	AED PLUS, PS SERIES W/BASIC CVR, LCD, VOICE RCDG, 50 HZ SPANISH, AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, ERC, SPANISH
20100001102011020	AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, FRENCH
20100001302011410	AED PLUS, PS SERIES NO GRAPHICS, W/AED CVR, LCD, VOICE RCDG, AHA, SWITZERLAND/ITALIAN
20100010102011320	ZOLL AED PLUS, PS SERIES, LCD, NO VOICE RCDG, W/BATTERIES, FED GOVT VALUE PKG
20100800101011050	AED PLUS, PS SERIES, W/PA CVR, ECG ON, LCD, NO VOICE RCDG, 50HZ, UK
20100800102011080	AED PLUS, PS SERIES, ECG ON, LCD, NO VOICE RCDG, GERMAN, AED PLUS, PS SERIES, W/AED CVR, ECG ON, LCD, NO VOICE RCDG, GERMAN
20100800102011110	AED PLUS, PS SERIES, W/AED CVR, ECG ON, LCD, NO VOICE RCDG, ITALIAN
20100800102011410	AED PLUS, PS SERIES, W/AED CVR, ECG ON, LCD, NO VOICE RCDG, AHA, SWITZERLAND/ITALIAN
20100800302011070	AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, ECG ON, LCD, NO VOICE RCDG, UK (PROPER)
20200000101011040	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, POLISH
20200000101011170	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, CZECH
20200000101011200	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, NORWEGIAN, AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RECORDING, 50HZ, NORWEGIAN
20200000101011220	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, SWEDISH
20200000101011270	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, DANISH
20200000101011290	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, RUSSIAN
20200000101011340	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, ARABIC
20200000101011450	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, HUNGARIAN
20200000101011520	AED PLUS, PS SERIES, BASIC CVR, LCD, NO VOICE RCDG, CROATIAN, 50HZ
20200000101011530	AED PLUS, PS SERIES, BASIC CVR, LCD, NO VOICE RCDG, SLOVENIAN
20200000101011550	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, TURK
20200000102011040	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, 50HZ, POLISH
20200000102011130	AED PLUS, PS SERIES, AED CVR, LCD, NO VOICE RCDG, AUS, 50HZ
20200000102011170	AED PLUS, PS SERIES, AED CVR, LCD, NO VOICE RCDG, 50HZ, CZECH
20200000102011190	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, GREEK
20200000102011200	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, 50HZ, NORWEGIAN, ZOLL AED PLUS, PS SERIES, AED CVR, LCD, NO VOICE RCDG, 50HZ, NORWEGIAN
20200000102011220	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, 50HZ, SWEDISH, AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, SWEDISH
20200000102011270	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, 50HZ, DANISH
20200000102011290	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, RUSSIAN
20200000102011330	AED PLUS, PS SERIES, AED CVR, LCD, NO VOICE RCDG, THAI, 50HZ
20200000102011520	AED PLUS, PS SERIES, AED CVR, LCD, NO VOICE RCDG, CROATIAN, 50HZ
20200000102019050	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, 50HZ, AIRLINE, UK
20200000102019080	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, 50HZ, AIRLINE, GERMAN
20200000302011020	AED PLUS, PS SERIES NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, FRENCH, AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, FRENCH

Catalog Number	Description
20200000302011080	AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, GERMAN
20200000302011160	AED PLUS, PS SERIES NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, DUTCH, AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, DUTCH
20200000302011210	AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, FINNISH
20200000303011050	AED PLUS, PS SERIES, W/LOW PROFILE CVR, LCD, NO VOICE RCDG, 50HZ, UK
20200001101011020	AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, FRENCH, ZOLL AEDPlus Interface Pictogramme/Couvercle PS avec enregistrement vocal
20200001101011050	AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, 50HZ, UK
20200001101011080	AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, GERMAN, ZOLL AED Plus "Public Safety", mit Sprachaufzeichnung
20200001101011100	AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, ERC, SPANISH
20200001101011110	AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, ITALIAN
20200001101011170	AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, 50HZ, CZECH
20200001101011180	AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, 50HZ, PORTUGUESE
20200001101011290	AED PLUS, PS SERIES W/BASIC CVR, LCD, VOICE RCDG, 50HZ, RUSSIAN
20200001101011530	AED PLUS, PS SERIES W/BASIC CVR, LCD, VOICE RCDG, 50HZ, SLOVENIAN
20200001102011110	AED Plus con Registrazione Audio Ambientale e con coperchio AED, AED PLUS, PS SERIES, W/AED CVR, LCD, VOICE RCDG, ITALIAN
20200001102011410	AED PLUS, PS SERIES W/AED CVR, LCD, VOICE RCDG, AHA, SWITZERLAND/ITALIAN
20200001302011020	AED PLUS, PS SERIES NO GRAPHICS, W/AED CVR, LCD, VOICE RCDG, FRENCH, AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, VOICE RCDG, FRENCH, Défibrillateur ZOLL AED Plus semi-automatique - Interface Professionnelle avec enregistrement de l'ambiance sonore
20200001302011110	AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, VOICE RCDG, ITALIAN
20200800101011290	AED PLUS, PS SERIES, AED CVR, ECG ON, LCD, NO VOICE RCDG, RUSSIAN
20200800102011040	AED PLUS, PS SERIES, AED CVR, ECG ON, LCD, NO VOICE RCDG, 50HZ, POLISH
20200800102019080	AED PLUS, PS SERIES, W/AED CVR, ECG ON, LCD, NO VOICE RCDG, 50HZ, AIRLINE, GERMAN
20200800302011080	AED PLUS, PS SERIES, AED CVR, ECG ON, LCD, NO VOICE RCDG, 50HZ, GERMAN
20300000101011200	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, NORWEGIAN
20300000101011210	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, FINNISH
20300000101011220	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, SWEDISH
20300000101011270	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, DANISH
20300000102011050	AED PLUS, PS SERIES, AED CVR, LCD, NO VOICE RCDG, 50HZ, DUTCH ARMY
20300000102011070	AED PLUS, PS SERIES, W/AED CVR, NO CARRY CASE, LCD, NO VOICE RCDG, UK (PROPER)
20300000102011160	AED PLUS, PS SERIES, AED CVR, LCD, NO VOICE RCDG, DUTCH ARMY, AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, DUTCH ARMY, AED Plus, semi-automatische defibrillator, NL Leger, NL
20300000102011210	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, FINNISH
20300000102011270	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, 50HZ, DANISH
20300000302011050	AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, DUTCH ARMY
20300000302011160	AED PLUS, PS SERIES, NO GRAPHICS, AED CVR, LCD, NO VOICE RCDG, DUTCH ARMY, AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, DUTCH ARMY
20300800102011080	AED PLUS, PS SERIES, W/AED CVR, ECG ON, LCD, NO VOICE RCDG, GERMAN

Catalog Number	Description
20400000001000020	AED PLUS, PA SERIES, W/BASIC CVR, NO LCD, NO VOICE RCDG, FRENCH
20400000001000080	AED PLUS, PA SERIES, W/BASIC CVR, NO LCD, NO VOICE RCDG, GERMAN, ZOLL "Public Safety" Serie AED Plus, Foundation-Modell
20400000001000160	AED PLUS, PA SERIES, W/BASIC CVR, NO LCD, NO VOICE RCDG, DUTCH
20400000001000180	AED PLUS, PA SERIES, W/BASIC CVR, NO LCD, NO VOICE RCDG, PORTUGUESE
21400710702011010	AED PLUS, PS SERIES, FULLY AUTOMATIC, W/AED CVR, LCD, NO VOICE RCDG, 60HZ, ENG
22300700502011050	AED PLUS, PS SERIES, FULLY AUTOMATIC, W/AED CVR, LCD, NO VOICE RCDG, UK
22300700502011080	AED PLUS, PS SERIES, FULLY AUTOMATIC, LCD, NO VOICE RCDG, GERMAN
22300700502011160	AED PLUS, PS SERIES, FULLY AUTOMATIC, LCD, NO VOICE RCDG, DUTCH
22300700702011280	AED PLUS, PS SERIES, FULLY AUTOMATIC, W/AED CVR, LCD, NO VOICE RCDG, AHA, INTL ENGLISH, AED PLUS, PS SERIES, FULLY AUTOMATIC, W/AED CVR, LCD, NO VOICE RCDG, INTL ENGLISH
22300703502011020	AED Plus, Entièrement Automatique, Interface avec pictogramme, FR, AED PLUS, PS SERIES, FULLY AUTOMATIC, LCD, NO VOICE RCDG, FRENCH, Défibrillateur ZOLL AED Plus entièrement automatique - interface pictogrammes
23000010102011320	AED PLUS, PS SERIES, LCD, NO VOICE RCDG, W/BATTERIES, MIL W/O WALL CAB
23100010102011320	AED PLUS, PS SERIES, LCD NO VOICE RCDG, W/BATTERIES, MIL W/WALL CAB
25100060310011070	AED PLUS, PS SERIES, LCD, NO VOICE RCDG, UK ENGLISH, AVIATION
20000000100011070	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, 50HZ, UK (PROPER)
8000-004016-01	ZOLL AED PLUS SEMI AUTOMATIC LAW ENFORCEMENT PACKAGE
20000000100011010	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, ENGLISH
8000-004017-01	ZOLL AED PLUS FULLY AUTOMATIC LAW ENFORCEMENT PACKAGE
20000700700011010	MAIN ASSY, PS SERIES, FULLY AUTOMATIC, LCD, NO VOICE RCDG, DMST
20200001101011550	AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, 50HZ, TURKISH
20000001100011550	MAIN ASSY, PS SERIES W/BASIC CVR, LCD, VOICE RCDG, 50HZ, TURKISH



**Accessory****REF**

<b>Therapy Electrodes</b>	
STAT-PADZ II ELECTRODE, SINGLE	8900-0801-01
STAT-PADZ II ADULT MULTI-FUNCTION ELECTRODES (1 PAIR), JAPANESE	8900-0801-36
STAT-PADZ II ELECTRODE, 12/CASE	8900-0802-01
STAT-PADZ II MULTI-FUNCTION ELECTRODES - 12/CASE, BRAZILIAN PORTUGUESE	8900-0802-24
STAT-PADZ II ELECTRODES, 12/CASE, JAPANESE	8900-0802-36
PEDI-PADZ II ELECTRODES - ONE PAIR	8900-0810-01
PEDI-PADZ II, AED PLUS, BRAZIL, SINGLES	8900-0810-24
PEDI-PADS II ELECTRODES, JAPAN, SINGLE	8900-0810-36
CPR-D-PADZ ONE PIECE ELECTRODE PAD WITH REAL CPR HELP	8900-0800-01
CPR-D-PADZ ELECTRODES, W/ACCESSORY KIT, BRAZILLIAN PORTUGUESE	8900-0800-24
CPR-D-PADZ ELECTRODES, W/ACCESSORY KIT, JAPAN	8900-0800-36
<b>Battery</b>	
TYPE 123 LITHIUM BATTERIES	8000-0807-01
<b>AED Plus Trainer</b>	
AED Plus Trainer 2	8008-0050-XX
AED Plus Fully Automatic Trainer 2	8008-000052-XX
<b>Other Accessories</b>	
REPLACEMENT PUBLIC SAFETY PASS COVER	8000-0812-01
REPLACEMENT PUBLIC ACCESS PASS COVER (GRAPHIC INTERFACE LABEL)	8000-0808-01
COMPACT LOW PROFILE PUBLIC SAFETY COVER	8000-0803-01
TRAINING CPR-D PADZ ELECTRODE, WITH 1 PAIR REP. GEL	8900-0804-01
TRAINING CPR-D REPLACEMENT GEL 5/CASE	8900-0803-01
PEDI-PADZ II TRAINING ELECTRODES (6/CASE)	8900-000861-01
<b>Non-Medical Device Accessories</b>	
REPLACEMENT SOFTCASE	8000-0802-01
LARGE PELICAN CASE	8000-0837-01
SMALL PELICAN CASE	8000-0836-01
REPLACEMENT SOFTCASE - POLICE	8000-0806-01
KIT SOFTCASE, AED PLUS TRAINER2	8000-0375-01
KIT, CABLE ADAPTER, UNIVERSAL ZOLL AED PLUS	8000-0804-01
USB IRDA ADAPTER	8000-0815
RS-232 IRDA ADAPTER	8000-0816
RESCUENET CODE REVIEW STANDARD SOFTWARE FOR WINDOWS	8000-0608-01
MOUNTING BRACKET	8000-0809-01
FULLY RECESSED WALL MOUNTING CABINET	8000-0811
RECESSED WALL MOUNTING CABINET	8000-0814
SURFACE WALL MOUNTING CABINET	8000-0817

STANDARD METAL WALL CABINET w/ZOLL LOGO	8000-0855
BRUSHED STAINLESS STEEL WALL CABINET	8000-0855-02
CLEAR AED PLUS WALL CABINET	8000-0856
AED WALL SIGN KIT, ONE FLUSH AND ONE 3-D WALL SIGN	8000-0825
AED PLUS 3-D WALL SIGN	9310-0738
KIT, LABEL, DECAL, ZOLL DEFIBRILLATOR EQUIPPED, PK OF 10, AED PLUS	8000-0849-01
TRAINER US AC ADAPTER	8000-0822
TRAINER PHONE CORD (REPLACEMENT)	8000-0821
TRAINER US AC ADAPTER	8000-0822
SIMULATOR / TESTER	8000-0819-XX

## MANUFACTURER'S DECLARATION OF CONFORMITY

### *AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002*

#### FULL QUALITY ASSURANCE PROCEDURES

This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

**Manufacturer's name:** ZOLL Medical Corporation

**Business address:** 269 Mill Road  
Chelmsford, MA 01824

**Medical device(s):** See Schedule 2

**Classification:** See Schedule 2

**GMDN code and term:** See Schedule 2

**Scope of application:** All products to which the full quality assurance procedure applies.

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

**Full quality assurance procedures  
certificates:**

No. QS6 079546 0021 (MDSAP Certificate)  
No. Q5 079546 0024 (QMS/ISO 13485 Certificate)  
No. G1 079546 0025 (EC Certificate)  
No. G2S 079546 0022 (EC Certificate Sterile Electrodes only)

**Standards applied:** See Schedule 1

# MANUFACTURER'S DECLARATION OF CONFORMITY

## AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

### FULL QUALITY ASSURANCE PROCEDURES

#### SCHEDULE 1

Conformity Standard	Description of Standard
ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14971: 2019	Medical devices – Application of risk management to medical devices
EN 60601-1: 2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2: ed3.0 (2007-03)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6: 2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-4: 2010	Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators
IEC 62366: 2014	Medical devices – Application of usability engineering to medical devices
MEDDEV 2.7.1: 2003	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
ISO 10993-1: 2010	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
ISO 10993-5: 2010	Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
ISO 10993-10: 2010	Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
EN ISO 15223-1: 2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 1041: 2008	Information supplied by the manufacturer of medical devices



# MANUFACTURER'S DECLARATION OF CONFORMITY

## AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

### FULL QUALITY ASSURANCE PROCEDURES

#### SCHEDULE 2

Catalog Number	Description	GMDN Code
20000000100011010	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, ENGLISH	47910
20000000100011050	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, 50HZ, UK	47910
20000000100011130	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, 50HZ, AUS	47910
20000000100011230	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, 60HZ, SPANISH	47910
20000000100011330	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, 50HZ, THAI	47910
20000000100011590	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, SINGAPORE	47910
20000001100011050	MAIN ASSY, PS SERIES, LCD, VOICE RCDG, 50HZ, UK	47910
20000700500011130	MAIN ASSY, FULLY AUTOMATIC, PS SERIES, LCD, NO VOICE RCDG, 50HZ, AUS	48047
70000000102011130	MAIN ASSY, PS SERIES, W/AED CVR, LCD, NO VOICE RECORDING, AUS/NZ, REFURB	47910
20000700700011010	MAIN ASSY, PS SERIES, FULLY AUTOMATIC, LCD, NO VOICE RCDG, DMST	48047

Accessory Description	Accessory Catalog Number	GMDN Code
<b>Therapy Electrodes</b>		
STAT-PADZ II ELECTRODE, SINGLE	8900-0801-01	45806
STAT-PADZ II ELECTRODE, 12/CASE	8900-0802-01	45806
PEDI-PADZ II ELECTRODES - ONE PAIR	8900-0810-01	42404
CPR-D-PADZ ONE PIECE ELECTRODE PAD WITH REAL CPR HELP	8900-0800-01	45806
<b>Battery</b>		
TYPE 123 LITHIUM BATTERIES	8000-0807-01	35848

<b>Non-Medical Device Accessories</b>		
AED Plus Trainer 2		8008-0050-XX
AED Plus Fully Automatic Trainer 2		8008-000052-XX
REPLACEMENT PUBLIC SAFETY PASS COVER		8000-0812-01
REPLACEMENT PUBLIC ACCESS PASS COVER (GRAPHIC INTERFACE LABEL)		8000-0808-01
COMPACT LOW PROFILE PUBLIC SAFETY COVER		8000-0803-01
TRAINING CPR-D PADZ ELECTRODE, WITH 1 PAIR REP. GEL		8900-0804-01
TRAINING CPR-D REPLACEMENT GEL 5/CASE		8900-0803-01
PEDI-PADZ II TRAINING ELECTRODES (6/CASE)		8900-000861-01
REPLACEMENT SOFTCASE		8000-0802-01
LARGE PELICAN CASE		8000-0837-01
SMALL PELICAN CASE		8000-0836-01
REPLACEMENT SOFTCASE - POLICE		8000-0806-01
KIT SOFTCASE, AED PLUS TRAINER2		8000-0375-01
KIT, CABLE ADAPTER, UNIVERSAL ZOLL AED PLUS		8000-0804-01
USB IRDA ADAPTER		8000-0815
RS-232 IRDA ADAPTER		8000-0816
RESCUENET CODE REVIEW STANDARD SOFTWARE FOR WINDOWS		8000-0608-01
MOUNTING BRACKET		8000-0809-01
FULLY RECESSED WALL MOUNTING CABINET		8000-0811
RECESSED WALL MOUNTING CABINET		8000-0814
SURFACE WALL MOUNTING CABINET		8000-0817
STANDARD METAL WALL CABINET w/ZOLL LOGO		8000-0855
BRUSHED STAINLESS STEEL WALL CABINET		8000-0855-02
CLEAR AED PLUS WALL CABINET		8000-0856
AED WALL SIGN KIT, ONE FLUSH AND ONE 3-D WALL SIGN		8000-0825
AED PLUS 3-D WALL SIGN		9310-0738

## MANUFACTURER'S DECLARATION OF CONFORMITY

### *AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002*

#### FULL QUALITY ASSURANCE PROCEDURES

KIT, LABEL, DECAL, ZOLL DEFIBRILLATOR EQUIPPED, PK OF 10, AED PLUS	8000-0849-01
TRAINER US AC ADAPTER	8000-0822
TRAINER PHONE CORD (REPLACEMENT)	8000-0821
TRAINER US AC ADAPTER	8000-0822
SIMULATOR / TESTER	8000-0819-XX

**Authorised signatory:**

\_\_\_\_\_  
Name: Elizabeth McMeniman  
Position: Director, Regulatory Affairs  
Location: Chelmsford, MA USA

3/4/2021

\_\_\_\_\_  
Date



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

# EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 079546 0023 Rev. 00**

**Manufacturer:**

**ZOLL Medical Corporation**

269 Mill Road  
Chelmsford MA 01824-4105  
USA

**EC-Representative:**

Zoll International Holding B.V.  
Newtonweg 18, 6662 PV Elst, THE NETHERLANDS

**Product Category(ies):**

**External Defibrillators, Automatic External  
Defibrillators, Multi-Parameters Monitoring  
Systems, Defibrillation Electrodes, Blood  
Cartridge and Crystalloid/Colloid Cartridge,  
Portable Ventilators with Patient Breathing  
Circuits.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:**

72145841

**Valid from:**

2019-07-30

**Valid until:**

2024-05-26

**Date,** 2019-07-30

Stefan Preiß  
Head of Certification/Notified Body



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## Facility(ies):

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

Zoll Medical Corporation  
271 Mill Road, Chelmsford MA 01824, USA

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