

Specificație tehnică completată

Model: AED 3, Producător: ZOLL Medical, Tara: SUA

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină completată de către autoritatea ofertantă
Defibrilator extern, semiautomat Cod 130400 Descriere Defibrilator semiautomat cu analiză ECG, încărcare automată și descărcare activată de operator. Defibrilatoarele externe semiautomate se utilizează în secțiile de medicină urgentă sau de către poliție și pompieri – personalul care este responsabil pentru urgențe medicale. Parametrul Specificația Defibrilator Tip semiautomat Acțiune manuală da Acțiune automată da Ghidare vocală în română sau rusă da Categorie de pacient: Adult și Pediatric da Secvențe de energie repartizate conform categoriei de pacient: Adult și Pediatric da Secvențe de energie pacient Adult ≥ 100 J Secvențe de energie pacient Pediatric ≥ 10 J Energia maximală de descărcare ≥ 300 J Forma de undă la ieșire bifazică Indicație de resuscitare cardio-respiratorie (CPR) da Ritmul pentru resuscitarea cardio-respiratorie (CPR) da Display Afișare semnal ECG da Afișare ritm cardiac da Afișare erori da Afișare mesaje informative da Analiza semnalului ECG Automată da Timpul de analiză < 15 s Captarea semnalului ECG prin intermediul padelelor Ritmului cardiac diapazon 30 - 300 BPM Acuratețea ± 1 BPM Autotestare zilnică, săptămînal, lunar da Timp de încărcare a energiei maxime de defibrilare < 10 s Baterie Tip reîncărcabil da Timp de operare > 200 de descărcări sau 4 ore continui de monitorizare a ECG Greutate ≤ 4.5 kg Alimentare electrică 220 V, 50 Hz Accesorii Electrozi defibrilare adult, de unică utilizare, cu termenul de valabilitate 2 ani la momentul livrării ≥ 3 set. pediatric, de unică utilizare, cu termenul de valabilitate 2 ani la momentul livrării ≥ 3 set.	Defibrilator extern, semiautomat DA Cod 130400 Descriere Defibrilator semiautomat cu analiză ECG, încărcare automată și descărcare activată de operator. Defibrilatoarele externe semiautomate se utilizează în secțiile de medicină urgentă sau de către poliție și pompieri – personalul care este responsabil pentru urgențe medicale. DA Parametrul Specificația Defibrilator Tip semiautomat DA Acțiune manuală DA Acțiune automată DA Ghidare vocală în română sau rusă DA Categorie de pacient: Adult și Pediatric DA Secvențe de energie repartizate conform categoriei de pacient: Adult și Pediatric DA Secvențe de energie pacient Adult ≥ 100 J DA Secvențe de energie pacient Pediatric ≥ 10 J DA Energia maximală de descărcare 200 J DA Forma de undă la ieșire bifazică rectiliniu (ca tehnologie cu un radament energetic mult mai eficient) Indicație de resuscitare cardio-respiratorie (CPR) DA Ritmul pentru resuscitarea cardio-respiratorie (CPR) DA Display Afișare semnal ECG DA Afișare ritm cardiac DA Afișare erori DA Afișare mesaje informative DA Analiza semnalului ECG Automată DA Timpul de analiză < 15 s DA Captarea semnalului ECG prin intermediul padelelor Ritmului cardiac diapazon 30 – 200 BPM Acuratețea ± 1 BPM DA Autotestare zilnică, săptămînal, lunar DA Timp de încărcare a energiei maxime de defibrilare < 10 s DA Baterie Tip reîncărcabil NU Timp de operare > 200 de descărcări sau 4 ore continui de monitorizare a ECG DA Greutate 2.5 kg DA NU Accesorii Electrozi defibrilare adult, de unică utilizare, cu termenul de valabilitate 5 ani la momentul livrării ≥ 3 set. DA cu sensor CPR pediatric, de unică utilizare, cu termenul de valabilitate 2 ani la momentul livrării ≥ 3 set. DA

Hîrtie pentru imprimantă doar în cazul dacă defibrilatorul este dotat cu imprimantă ≥ 3 buc Geantă de transport/depozitare defibrilator geanta să fie prevăzută pentru transportarea și depozitarea defibrilatorului. Să fie dotată cu buzunare pentru toate accesoriile da	Hîrtie pentru imprimantă doar în cazul dacă defibrilatorul este dotat cu imprimantă ≥ 3 buc NU Geantă de transport/depozitare defibrilator geanta să fie prevăzută pentru transportarea și depozitarea defibrilatorului. Să fie dotată cu buzunare pentru toate accesoriile DA pentru un set de electrozi de fiecare.
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ZOLL AED 3[®] BLS



Technical Specifications

High-quality CPR When and Where You Need It Most

The ZOLL AED 3[®] BLS provides enhanced Real CPR Help[®], which measures the actual depth and rate of each compression and displays it on the CPR Dashboard™. In addition to the CPR Dashboard, the ZOLL AED 3 BLS displays the patient's ECG, the remaining time for the current CPR cycle, the elapsed time since the patient had collapsed, and the number of shocks delivered. And to ensure optimal visibility, the ZOLL AED 3 BLS can be positioned flat or upright like an ALS device.

Shorten the Learning Curve

If you have an R Series in your hospital, using the ZOLL AED 3 CPR Dashboard will be seamless. The same numerical values are displayed, and the same audible feedback and metronome help you comply with the 2015 American Heart Association Guidelines of 100 to 120 compressions per minute. Whether you rescue a patient in the cafeteria, the parking garage, or near a clinical area, Real CPR Help will guide high-quality CPR, which has been linked to improved patient outcomes.

By the Numbers

The 2015 CPR Guidelines state that "Data-driven performance-focused debriefing has been shown to improve performance of resuscitation teams. We highly recommend their use for teams managing patients in cardiac arrest."¹ Using ZOLL's RescueNet[®] CaseReview, detailed rescue performance data can be exported quickly and easily via USB or transferred directly using the WiFi capability. Data on CPR rate, depth, release velocity, and chest compression fraction can easily be evaluated and used to improve future responder performance.

Always Code-Ready

The WiFi capabilities of the ZOLL AED 3 BLS allow the AED to report its state of readiness, including batteries and electrodes, to Defibrillator Dashboard™, ZOLL's asset management database. Biomedical engineering can determine quickly if an AED in the hospital's fleet needs attention before it is needed. The WiFi also provides automatic clock synchronization, which is critically important at the beginning and end of daylight saving time.

¹Resuscitation. 2015;95:288-301



The metrics of Real CPR Help® can be seen on the dashboard.



Data containing CPR quality can be downloaded after the event via WiFi and reviewed quickly with the code team to evaluate and identify areas of improvement.



Child button will illuminate when pediatric pad is attached.

ZOLL AED 3 BLS Specifications

Defibrillator

Protocol: Semi-automatic

Waveform: ZOLL Rectilinear Biphasic™

Defibrillator Charge Hold Time:
30 seconds

Energy Selection: Factory preprogrammed selection (Adult: 120 J, 150 J, 200 J; Child: 50 J, 70 J, 85 J). User configurable.

Patient Safety: All patient connections are electrically isolated

Charge Time: Less than 10 seconds with new battery

Pre-shock Pause: 8 seconds with new battery

Self-test: User-configurable automatic self-test every day or every 7 days. Default: Every 7 days. Monthly full-energy test (200 J).

Automatic Self-test Checks: Battery capacity, status and expiration; electrode connection and expiration; ECG and charge/discharge circuits; microprocessor hardware and software; CPR circuitry and pads sensor; audio circuitry

CPR Metronome Rate: Constant 105 (+/- 2) CPM

Depth Measurement: 1.9 cm to 10.2 cm; 0.75 in to 4 in

Defibrillation Advisory: Evaluates electrode connection and patient ECG to determine if defibrillation is required

Shockable Rhythms: Ventricular fibrillation with average amplitude >100 microvolts and wide complex ventricular tachycardia with rates greater than 150 BPM for adults, 200 BPM for pediatrics. For ECG analysis algorithm sensitivity and specificity, refer to the ZOLL AED 3 Administrator's Guide.

Patient Impedance Measurement Range: 10 to 300 ohms

Defibrillator: Protected ECG circuitry

Display Format: High-resolution LCD with capacitive touch panel

Display Screen Size: 5.39 cm x 9.5 cm; 2.12 in x 3.74 in

Display Sweep Speed: 25 mm/sec

Display Viewing Speed:
3.84 seconds

Data Recording and Storage: User-configurable for 1 or 2 clinical events for total of 120 minutes. Includes ECG, impedance measurements, device prompts, and CPR data. With voice recording enabled, same data with synchronous audio added for total of 60 minutes.

Data Recovery: Controlled by touchscreen, uploaded to USB memory stick, or RescueNet CaseReview or CodeReview, over a WiFi network

Internal Clock Synchronization: Coordinated Universal Time (UTC) synchronization occurs when communicating with hospital Wi-Fi.

Device

Size: (H x W x D) 12.7 cm x 23.6 cm x 24.7 cm; 5.0 in x 9.3 in x 9.7 in

Weight: 2.5 kg; 5.5 lbs

Power: Lithium manganese dioxide battery pack

Wireless: 802.11 a/b/g/n

Security Protocols: WPA1, WPA 2, WPA Personal, WPA Enterprise

Port: USB 2.0

Audio Recording: User-configurable on/off (default=off)

Device Classification: Class III and internally powered per EN 60601-1

Design Standards: Meets applicable requirements of EN 60601-1, EN 60601-1-11, IEC 60601-2-4

Environmental

Operating Temperature: 0° to 50°C; 32° to 122°F

Storage Temperature: -30° to 70°C; -22° to 158°F

Humidity: 10% to 95% relative humidity, non-condensing

Vibration: IEC 60068-2-64, Random, Spectrum A.4, Table A.8, Cat. 3b; RTCA/DO-160G, Fixed Wing Aircraft, Section 8.6, Test Cat. H, Aircraft Zone 1 and 2; EN1789, Sweep per EN 60068-2-6 Test Fc

Shock: IEC 60068-2-27; 100G

Altitude: -381 m to 4573 m; 1,250 to 15,000 ft

Particle and Water Ingress: IP55

Drop Test: 1 meter; 3.28 ft

Battery

Type: Disposable, sealed lithium manganese dioxide

Battery Standby Life (once installed)*: 5 years with weekly self-test. Battery end of life indicated by blank status window (typical remaining shocks: 9).

Battery Shelf Life: Store for up to 2 years at 23°C (77°F) prior to installing in ZOLL AED 3 BLS to maintain battery life detailed above.

Temperature: 0°C to 50°C (32°F to 122°F)

Humidity: 10% to 95% (non-condensing)

Weight: 317.5 grams; 0.7 lbs

Size: (H x W x D) 27.75 mm x 133 mm x 88 mm; 1.0 in x 5.16 in x 3.5 in

Nominal Voltage: 12 volts

ZOLL AED 3 BLS Carry Bag

Size: (H x W x D) 29.2 cm x 27.4 cm x 17.8 cm; 11.5 in x 10.8 in x 7.0 in

Weight: 3.4 kg; 7.5 lbs (ZOLL AED 3 BLS with battery installed and an electrode pre-connected in carry bag)

Holds: ZOLL AED 3 BLS with battery inserted and back-up set of electrodes

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For subsidiary addresses and fax numbers, as well as other global locations, please go to www.zoll.com/contacts.

*Battery standby life will be shorter in areas with low WiFi signal strength and/or more complex WiFi authentication protocols.

Specifications subject to change without notice.

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ZOLL

ZOLL AED 3[®] BLS

ZOLL[®]



*Designed with
Hospitals in Mind*

HIGH-QUALITY CPR WHEN AND WHERE YOU NEED IT MOST

High-quality CPR is the cornerstone of a system of care that can optimize resuscitation outcomes. The American Heart Association (AHA) and European Resuscitation Council (ERC) 2020 Guidelines underscore just how important CPR quality is for a successful resuscitation program. To deliver high-quality CPR, nurses and doctors need to focus on depth, rate, limited interruptions, and release. ZOLL® offers the same unique CPR feedback technology in our AEDs as we do on our manual defibrillators, allowing continuity of patient care, no matter where they may encounter cardiac issues in the hospital.

ZOLL's CPR Uni-padz® electrodes work on both adult and pediatric patients, eliminating the need to maintain two separate sets of pads. Their universal design gives rescuers a single, versatile solution for sudden cardiac arrest victims. When treating a child with CPR Uni-padz electrodes, simply activate child mode. CPR Uni-padz have an industry-leading shelf life of five years.



More than CPR. This is Real CPR Help®.

The ZOLL AED 3® BLS features Real CPR Help, technology that coaches clinicians on the depth and rate of compressions necessary for high-quality CPR. For clinicians who rarely perform CPR, this technology helps them achieve optimal rate and depth. For patients, it offers a greater chance of surviving sudden cardiac arrest (SCA). The ZOLL AED 3 BLS is also the only AED on the market that offers real-time CPR feedback for pediatric patients.

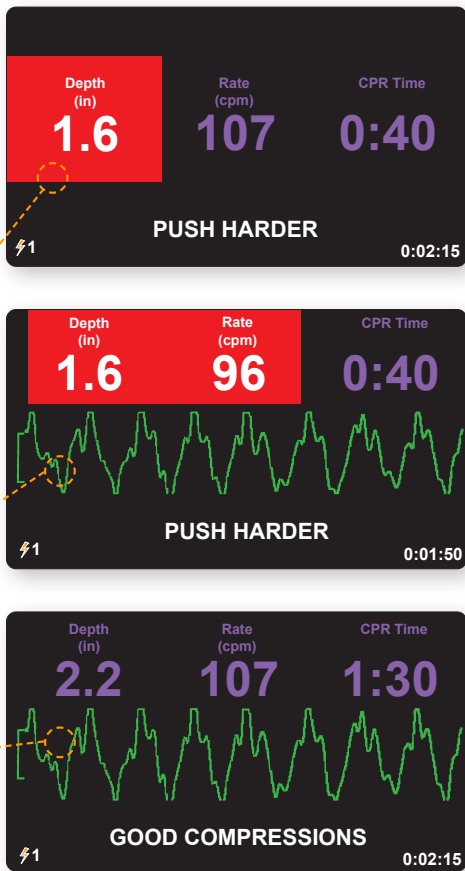
Minimizes time to shock

Using ZOLL's RapidShock™ Analysis, the ZOLL AED 3 BLS analyzes a victim's cardiac rhythm during continuous, uninterrupted CPR, performs a three-second reconfirmation analysis, and then delivers a shock if needed.

When RapidShock Analysis advises a shock, in most cases CPR only pauses for a total of 5 seconds — to analyze and deliver the shock. Offering one of the fastest times to shock in the market.

Synergy with manual ZOLL defibrillators

Chances are high that a clinician will be one of the first responders to an SCA in a hospital setting. If they are already familiar with the CPR Dashboard™ on R Series® or X Series®, then the dashboard of the ZOLL AED 3 BLS will be intuitive to use and valuable in helping them achieve high-quality CPR. This familiarity can bring speed of therapy to the patient.



Data for Benchmarking

The ZOLL AED3 BLS automatically powers on five minutes after a rescue to transmit clinical case data to RescueNet® CaseReview via Wifi. This case push feature ensures key metrics are delivered to QA/QI personnel. CaseReview collects, collates, and manages code data to simplify debriefing. It also stores clinical event files from other ZOLL devices, such as the R Series and X Series.

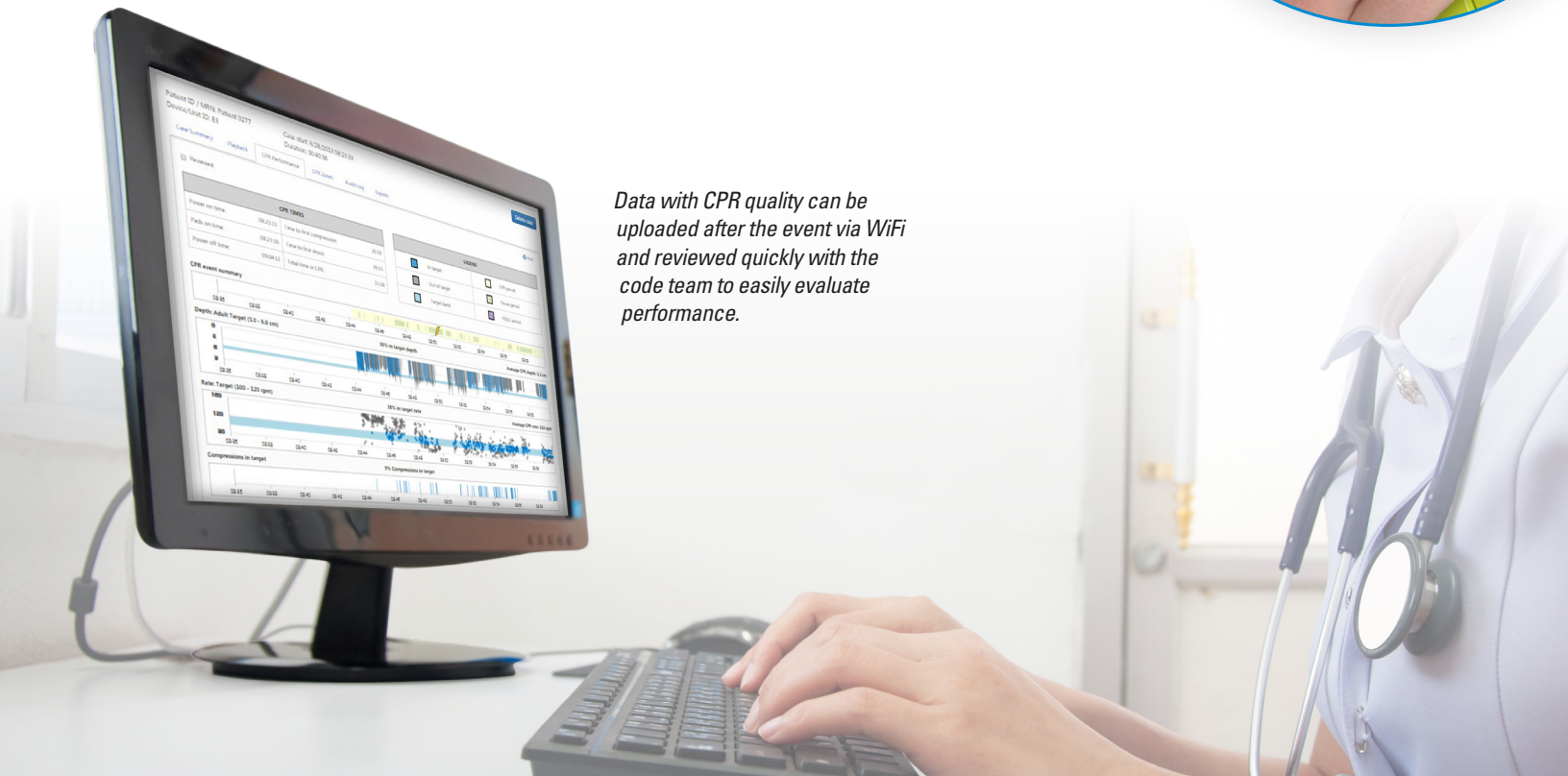
Always Code Ready

The ZOLL AED 3 BLS reports its state of readiness into Defibrillator Dashboard™, ZOLL's asset management system. Biomedical engineering can quickly check and ensure every AED in the hospital is ready to use.

Network clock synchronization for the beginning and end of daylight saving time occurs whenever the ZOLL AED 3 BLS communicates with the hospital WiFi system, ensuring your AED is always using the correct timestamp any time it's needed for resuscitation.



Data with CPR quality can be uploaded after the event via WiFi and reviewed quickly with the code team to easily evaluate performance.



1 Fumagalli et al. *Heart Rhythm*. 2018;15:248.

ZOLL MEDICAL CORPORATION

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The product has not received regulatory approval by the Food and Drug Administration.

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MCN HP 2110 0546

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ZOLL®



DECLARATION OF CONFORMITY



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The Netherlands

Product: ZOLL AED 3
ZOLL AED 3 Automatic
ZOLL AED 3 BLS
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.

Name: Elizabeth Haines
Position: Director, Regulatory Affairs
Location: Chelmsford, MA USA

March 29, 2021
Date

Catalog Number	Description
8501-001101-06	SEMI-AUTOMATIC, ZOLL AED 3, ENGLISH, CANADIAN, AHA
8501-001101-26	SEMI-AUTOMATIC, ZOLL AED 3, FRENCH CANADIAN, AHA
8501-001102-06	AUTOMATIC, ZOLL AED 3, ENGLISH, CANADIAN, AHA
8501-001102-26	AUTOMATIC, ZOLL AED 3, FRENCH CANADIAN, AHA
8502-001103-06	BLS, ZOLL AED 3, ENGLISH, CANADIAN, AHA
8502-001103-26	BLS, ZOLL AED 3, FRENCH CANADIAN, AHA
8503-001103-06	BLS, W/O CARRY CASE, ZOLL AED 3, ENGLISH, CANADIAN, AHA
8503-001103-26	BLS, W/O CARRY CASE, ZOLL AED 3, FRENCH CANADIAN, AHA
8501-001201-07	SEMI-AUTOMATIC, ZOLL AED 3, ENGLISH UK ERC
8501-001201-12	SEMI-AUTOMATIC, ZOLL AED 3, INTL ENGLISH ERC
8501-001201-23	SEMI-AUTOMATIC, ZOLL AED 3, SPANISH AHA
8501-001202-23	AUTOMATIC, ZOLL AED 3, SPANISH AHA
8501-001202-28	AUTOMATIC, ZOLL AED 3, INTL ENGLISH AHA
8502-001103-01	BLS, ZOLL AED 3, ENGLISH, AHA
8502-001103-06	BLS, ZOLL AED 3, ENGLISH, CANADIAN, AHA
8502-001203-07	BLS, ZOLL AED 3, ENGLISH UK ERC
8502-001203-10	BLS, ZOLL AED 3, SPANISH ERC
8502-001203-23	BLS, ZOLL AED 3, SPANISH AHA
8502-001203-28	BLS, ZOLL AED 3, INTL ENGLISH AHA
8503-001103-01	BLS, W/O CARRY CASE, ZOLL AED 3, ENGLISH, AHA
8503-001103-06	BLS, W/O CARRY CASE, ZOLL AED 3, ENGLISH, CANADIAN, AHA
8513-001103-01	BLS, W/O CARRY CASE, ZOLL AED 3, PLUSRX, ENGLISH, AHA
8501-001202-42	AUTOMATIC, ZOLL AED 3, FRENCH AHA
8502-001203-08	BLS, ZOLL AED 3, GERMAN ERC
8502-001203-09	BLS, ZOLL AED 3, GERMAN AHA
8502-001203-28	BLS, ZOLL AED 3, INTL ENGLISH AHA
8502-001203-41	BLS, ZOLL AED 3, ITALIAN AHA
8502-001203-42	BLS, ZOLL AED 3, FRENCH AHA
8501-001201-02	SEMI-AUTOMATIC, ZOLL AED 3, FRENCH ERC
8501-001201-04	SEMI-AUTOMATIC, ZOLL AED 3, POLISH, ERC
8501-001201-08	SEMI-AUTOMATIC, ZOLL AED 3, GERMAN ERC
8501-001201-10	SEMI-AUTOMATIC, ZOLL AED 3, SPANISH ERC
8501-001201-11	SEMI-AUTOMATIC, ZOLL AED 3, ITALIAN ERC
8501-001201-17	SEMI-AUTOMATIC, ZOLL AED 3, CZECH, ERC
8501-001201-64	SEMI-AUTOMATIC, ZOLL AED 3, ROMANIAN, ERC
8502-001203-17	BLS, ZOLL AED 3, CZECH, ERC
8501-001201-16	SEMI-AUTOMATIC, ZOLL AED 3, DUTCH ERC
8501-001201-18	SEMI-AUTOMATIC, ZOLL AED 3, IBERIAN PORTUGUESE, ERC
8501-001201-61	SEMI-AUTOMATIC, ZOLL AED 3, BELGUIM, ERC
8501-001201-62	SEMI-AUTOMATIC, ZOLL AED 3, DUTCH MILITARY, ERC
8501-001201-63	SEMI-AUTOMATIC, ZOLL AED 3, LUXEMBOURG, ERC
8501-001202-02	AUTOMATIC, ZOLL AED 3, FRENCH ERC
8501-001202-08	AUTOMATIC, ZOLL AED 3, GERMAN ERC

Catalog Number	Description
8501-001202-10	AUTOMATIC, ZOLL AED 3, SPANISH ERC
8501-001202-11	AUTOMATIC, ZOLL AED 3, ITALIAN ERC
8501-001202-12	AUTOMATIC, ZOLL AED 3, INTL ENGLISH ERC
8501-001202-16	AUTOMATIC, ZOLL AED 3, DUTCH ERC
8501-001202-61	AUTOMATIC, ZOLL AED 3, BELGIUM, ERC
8501-001202-63	AUTOMATIC, ZOLL AED 3, LUXEMBOURG, ERC
8502-001203-02	BLS, ZOLL AED 3, FRENCH ERC
8502-001203-07	BLS, ZOLL AED 3, ENGLISH UK ERC
8502-001203-10	BLS, ZOLL AED 3, SPANISH ERC
8502-001203-11	BLS, ZOLL AED 3, ITALIAN ERC
8502-001203-12	BLS, ZOLL AED 3, INTL ENGLISH ERC
8502-001203-16	BLS, ZOLL AED 3, DUTCH
8502-001203-23	BLS, ZOLL AED 3, SPANISH AHA
8502-001203-61	BLS, ZOLL AED 3, BELGIUM, ERC
8502-001203-63	BLS, ZOLL AED 3, LUXEMBOURG, ERC
8501-001201-21	SEMI-AUTOMATIC, ZOLL AED 3, FINNISH
8501-001201-22	SEMI-AUTOMATIC, ZOLL AED 3, SWEDISH ERC
8501-001201-27	SEMI-AUTOMATIC, ZOLL AED 3, DANISH ERC
8501-001202-22	AUTOMATIC, ZOLL AED 3, SWEDISH ERC
8501-001202-27	AUTOMATIC, ZOLL AED 3, DANISH ERC
8502-001203-20	BLS, ZOLL AED 3, NORWEGIAN
8502-001203-21	BLS, ZOLL AED 3, FINNISH
8502-001203-22	BLS, ZOLL AED 3, SWEDISH
8502-001203-27	BLS, ZOLL AED 3, DANISH
8501-001201-07	SEMI-AUTOMATIC, ZOLL AED 3, ENGLISH UK ERC
8501-001202-07	AUTOMATIC, ZOLL AED 3, ENGLISH UK ERC
8501-001201-45	SEMI-AUTOMATIC, ZOLL AED 3, HUNGARIAN, ERC
8502-001203-45	BLS, ZOLL AED 3, HUNGARIAN, ERC
8501-001201-28	SEMI-AUTOMATIC, ZOLL AED 3, INTL ENGLISH AHA
8501-001201-41	SEMI-AUTOMATIC, ZOLL AED 3, ITALIAN AHA
8502-001203-04	BLS, ZOLL AED 3, POLISH, ERC
8502-001203-62	BLS, ZOLL AED 3, DUTCH MILITARY, ERC
8501-001201-20	SEMI-AUTOMATIC, ZOLL AED 3, NORWEGIAN
8501-001202-64	AUTOMATIC, ZOLL AED 3, ROMANIAN, ERC
8502-001203-64	BLS, ZOLL AED 3, ROMANIAN, ERC
8501-001201-56	SEMI-AUTOMATIC, ZOLL AED 3, INDONESIAN, AHA
8501-001201-71	SEMI-AUTOMATIC, ZOLL AED 3, MALAYSIAN AHA
8501-001202-33	AUTOMATIC, ZOLL AED 3, THAI AHA
8501-001201-33	SEMI-AUTOMATIC, ZOLL AED 3, THAI, AHA
8502-001203-33	BLS, ZOLL AED 3, THAI, AHA
8501-001202-56	AUTOMATIC, ZOLL AED 3, INDONESIAN, AHA
8501-001202-71	AUTOMATIC, ZOLL AED 3, MALAYSIAN AHA
8502-001203-56	BLS, ZOLL AED 3, INDONESIAN, AHA

Catalog Number	Description
8502-001203-71	BLS, ZOLL AED 3, MALAYSIAN AHA
8501-001201-19	SEMI-AUTOMATIC, ZOLL AED 3, GREEK ERC
8501-001201-51	SEMI-AUTOMATIC, ZOLL AED 3, LATVIAN ERC
8501-001201-73	SEMI-AUTOMATIC, ZOLL AED 3, SLOVAKIAN ERC
8501-001202-19	AUTOMATIC, ZOLL AED 3, GREEK ERC
8501-001202-51	AUTOMATIC, ZOLL AED 3, LATVIAN ERC
8501-001202-73	AUTOMATIC, ZOLL AED 3, SLOVAKIAN ERC
8502-001203-19	BLS, ZOLL AED 3, GREEK ERC
8502-001203-51	BLS, ZOLL AED 3, LATVIAN ERC
8502-001203-73	BLS, ZOLL AED 3, SLOVAKIAN ERC
8501-001201-35	SEMI-AUTOMATIC, ZOLL AED 3, HEBREW AHA
8501-001202-35	AUTOMATIC, ZOLL AED 3, HEBREW AHA
8502-001203-35	BLS, ZOLL AED 3, HEBREW AHA
8501-001201-34	SEMI-AUTOMATIC, ZOLL AED 3, ARABIC AHA
8501-001202-34	AUTOMATIC, ZOLL AED 3, ARABIC AHA
8502-001203-34	BLS, ZOLL AED 3, ARABIC AHA
8501-001101-01	SEMI-AUTOMATIC, ZOLL AED 3, ENGLISH, AHA
8501-001102-01	AUTOMATIC, ZOLL AED 3, ENGLISH, AHA
8525-001101-01	SEMI-AUTOMATIC, ZOLL AED 3, ARC PKG, PLUSRX, ENGLISH, AHA
8529-001101-01	SEMI-AUTOMATIC, ZOLL AED 3, WALL CABINET, PLUSRX, ENGLISH, AHA
8529-001102-01	AUTOMATIC, ZOLL AED 3, WALL CABINET, PLUSRX, ENGLISH, AHA
8511-001101-01	SEMI-AUTOMATIC, ZOLL AED 3, PLUSRX, ENGLISH, AHA
8511-001102-01	AUTOMATIC, ZOLL AED 3, PLUSRX, ENGLISH, AHA
8525-001102-01	AUTOMATIC, ZOLL AED 3, ARC PKG, PLUSRX, ENGLISH, AHA
8514-001101-01	SEMI-AUTOMATIC, ZOLL AED 3, PLUSTRAC PROFESSIONAL 1, ENGLISH, AHA
8514-001102-01	AUTOMATIC, ZOLL AED 3, PLUSTRAC PROFESSIONAL 1, ENGLISH, AHA
8515-001101-01	SEMI-AUTOMATIC, ZOLL AED 3, PLUSTRAC PROFESSIONAL 5, ENGLISH, AHA
8515-001102-01	AUTOMATIC, ZOLL AED 3, PLUSTRAC PROFESSIONAL 5, ENGLISH, AHA
8531-001201-41	SEMI-AUTOMATIC, ZOLL AED 3, ITALIAN AHA
8531-001201-42	SEMI-AUTOMATIC, ZOLL AED 3, FRENCH AHA
8531-001202-41	AUTOMATIC, ZOLL AED 3, ITALIAN AHA
8531-001202-42	AUTOMATIC, ZOLL AED 3, FRENCH AHA
8532-001203-41	BLS, ZOLL AED 3, ITALIAN AHA
8532-001203-42	BLS, ZOLL AED 3, FRENCH AHA
8501-001201-44	SEMI-AUTOMATIC, ZOLL AED 3, HINDI AHA
8501-001202-44	AUTOMATIC, ZOLL AED 3, HINDI AHA
8502-001203-44	BLS, ZOLL AED 3, HINDI AHA
8501-001201-48	SEMI-AUTOMATIC, ZOLL AED 3, LITHUANIAN ERC
8501-001202-48	AUTOMATIC, ZOLL AED 3, LITHUANIAN ERC
8502-001203-48	BLS, ZOLL AED 3, LITHUANIAN ERC
8501-001201-52	SEMI-AUTOMATIC, ZOLL AED 3, CROATIAN ERC
8501-001202-52	AUTOMATIC, ZOLL AED 3, CROATIAN ERC
8502-001203-52	BLS, ZOLL AED 3, CROATIAN ERC

Catalog Number	Description
8501-001201-53	SEMI-AUTOMATIC, ZOLL AED 3, SLOVENIAN ERC
8501-001202-53	AUTOMATIC, ZOLL AED 3, SLOVENIAN ERC
8502-001203-53	BLS, ZOLL AED 3, SLOVENIAN ERC
8501-001201-55	SEMI-AUTOMATIC, ZOLL AED 3, TURKISH ERC
8501-001202-55	AUTOMATIC, ZOLL AED 3, TURKISH ERC
8502-001203-55	BLS, ZOLL AED 3, TURKISH ERC
8501-001201-70	SEMI-AUTOMATIC, ZOLL AED 3, VIETNAMESE AHA
8501-001202-70	AUTOMATIC, ZOLL AED 3, VIETNAMESE AHA
8502-001203-70	BLS, ZOLL AED 3, VIETNAMESE AHA
8501-001201-72	SEMI-AUTOMATIC, ZOLL AED 3, BULGARIAN ERC
8501-001202-72	AUTOMATIC, ZOLL AED 3, BULGARIAN ERC
8502-001203-72	BLS, ZOLL AED 3, BULGARIAN ERC
8501-001201-74	SEMI-AUTOMATIC, ZOLL AED 3, TAGALOG AHA
8501-001202-74	AUTOMATIC, ZOLL AED 3, TAGALOG AHA
8502-001203-74	BLS, ZOLL AED 3, TAGALOG AHA
8501-001201-81	SEMI-AUTOMATIC, ZOLL AED 3, THAI JAPAN AHA
8501-001202-81	AUTOMATIC, ZOLL AED 3, THAI JAPAN AHA
8502-001203-81	BLS, ZOLL AED 3, THAI JAPAN AHA
8526-001101-01	SEMI-AUTOMATIC, ZOLL AED 3, LAW ENFORCEMENT PKG, ENGLISH, AHA
8526-001102-01	AUTOMATIC, ZOLL AED 3, LAW ENFORCEMENT PKG, ENGLISH, AHA
8532-001203-36	BLS, ZOLL AED 3, JAPANESE, JRC
8533-001203-36	BLS, ZOLL AED 3, W/O CARRY CASE, JAPANESE, JRC
8531-001201-36	SEMI-AUTOMATIC, ZOLL AED 3, JAPANESE, JRC
8562-001206-22	BLS, AVIATION, ZOLL AED 3, SWEDISH ERC
8522-001103-01	BLS, ZOLL AED 3, ENGLISH AHA, PACKAGE 1
8523-001103-01	BLS, ZOLL AED 3, ENGLISH AHA, PACKAGE 2
8501-001201-49	SEMI-AUTOMATIC, ZOLL AED 3, SERBIAN
8501-001202-49	AUTOMATIC, ZOLL AED 3, SERBIAN ERC
8502-001203-49	BLS, ZOLL AED 3, SERBIAN ERC

Annex to Declaration of Conformity Accessory List

ZOLL declares that the products listed below conform to European Council Directive 93/42/EEC (Medical Device Directive).
(X represents any numeric digit)

Accessory

Defibrillation Accessories	
CPR UNI-PADZ	8900-000260
CPR UNI-PADZ	8900-000270
CPR UNI-PADZ	8900-000280
CPR UNI-PADZ, (U.S. only)	8900-000280-01
CPR-D-PADZ ONE PIECE ELECTRODE PAD WITH REAL CPR HELP	8900-0800-01
CPR STAT-PADZ ELECTRODE, SINGLE	8900-0402
STAT-PADZ II ELECTRODE, SINGLE	8900-0801-01
PEDI-PADZ II ELECTRODES - ONE PAIR	8900-0810-01
ONESTEP BASIC ELECTRODES WITH GREEN CONNECTOR	8900-000250-05
ONESTEP CPR A/A ELECTRODES WITH GREEN CONNECTOR	8900-000251-05
ONESTEP PEDIATRIC ELECTRODES WITH GREEN CONNECTOR	8900-000252-05
Battery Accessories	
ZOLL AED 3 BATTERY PACK	8000-000696
ZOLL AED 3 AVIATION BATTERY PACK	8000-000697
ZOLL AED 3 BATTERY PACK, JAPANESE	8000-000696-36
ZOLL AED 3 AVIATION BATTERY PACK, SWEDISH	8000-000697-22
Simulation/Training Accessories	
CPR UNI-PADZ TRAINING KIT	8900-000264
CPR UNI-PADZ, II TRAINING KIT	8900-000274
CPR UNI-PADZ, III TRAINING KIT	8900-000284
Non-Medical Device Accessories	
AED PLUS 2 CARRY CASE	8000-001250
POUCH, BATTERY, ZOLL AED 3	8000-001251
SHOULDER STRAP, CARRY CASE, ZOLL AED 3	8000-001252
SMALL RIGID PLASTIC CARRY CASE, ZOLL AED 3	8000-001253
LARGE RIGID PLASTIC CARRY CASE, ZOLL AED 3	8000-001254
BRACKET, WALL MOUNT, ZOLL AED 3	8000-001255
WALL CABINET, STANDARD SURFACE, ZOLL AED 3	8000-001256
WALL CABINET, SEMI-RECESSED, ZOLL AED 3	8000-001257
WALL CABINET, FULLY-RECESSED, ZOLL AED 3	8000-001258
STROBE LIGHT, AED PLUS SERIES	8000-001259
ILCOR FLUSH WALL SIGN (AED)	8000-001260
ILCOR 3-D WALL SIGN (AED)	8000-001261
ILCOR FLUSH WALL SIGN (DAE)	8000-001262
ILCOR 3-D WALL SIGN (DAE)	8000-001263

ILCOR FLUSH WALL SIGN (DEA)	8000-001264
ILCOR 3-D WALL SIGN (DEA)	8000-001265
BRACKET, WALL MOUNT, CASE, ZOLL AED 3	8000-001266
STROBE LIGHT W/PLATE, AED PLUS SERIES	8000-001267
ZOLL AED SIMULATOR	8000-000925
SOFT CARRY CASE, ZOLL AED 3	8000-001280

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 procedures 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

SCHEDULE 1

Conformity Standard	Description of Standard
ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 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
IEC 60601-1-2: 2014	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
EN 60601-1-9: 2013	Medical Electrical Equipment - Part 1-9: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Environmentally Conscious Design
EN 60601-1-11: 2010	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
EN 1041: 2008	Information supplied by the manufacturer of medical devices
EN 50581: 2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
IEC 62366: 2014	Medical devices – Application of usability engineering to medical devices
IEC 60601-2-4: 2010	Medical electrical equipment - Part 2-4: Particular requirements for the Safety of Cardiac Defibrillators
EN 62304: 2006	Medical device software – Software life-cycle processes

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

Conformity Standard	Description of Standard
EN 1789: 2014	Medical vehicles and their equipment – Road ambulances
IEC 60086-4	Primary Batteries - Part 4: Safety of Lithium Batteries ¹
RTCA/DO-227A amended by TSO C142b	Minimum Operational Performance Standards for Non-Rechargeable Lithium Batteries as amended by Appendix 1 of TSO-C142b ¹
MEDDEV 2.7.1: 2016	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
EN ISO 14155: 2011	Clinical investigation of medical devices for human subjects – Good clinical practice
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

¹ Applies to the AED 3 Aviation Battery Pack only

SCHEDULE 2

Catalog Number	Description	Class	GMDN Code
1128-001201-13	MAIN ASSEMBLY, SEMI-AUTOMATIC, ZOLL AED 3, AUSTRALIA	IIb	47910
1128-001202-13	MAIN ASSEMBLY, AUTOMATIC, ZOLL AED 3, AUSTRALIA	IIb	48047
1128-001203-13	MAIN ASSEMBLY, BLS, ZOLL AED 3, AUSTRALIA	IIb	48049
1128-001204-13	MAIN ASSEMBLY, AVIATION SEMI-AUTOMATIC, ZOLL AED 3, AUSTRALIA	IIb	47910
1128-001205-13	MAIN ASSEMBLY, AVIATION AUTOMATIC, ZOLL AED 3, AUSTRALIA	IIb	48047
1128-001206-13	MAIN ASSEMBLY, AVIATION BLS, ZOLL AED 3, AUSTRALIA	IIb	48049

Accessory Description	Accessory Catalog Number	GMDN Code
Defibrillation Accessories		
CPR UNI-PADZ	8900-000260	45806, 42404
CPR UNI-PADZ	8900-000270	45806, 42404
CPR UNI-PADZ	8900-000280	45806, 42404
CPR UNI-PADZ, (U.S. only)	8900-000280-01	45806, 42404
CPR-D-PADZ ONE PIECE ELECTRODE PAD WITH REAL CPR HELP	8900-0800-01	45806
CPR STAT-PADZ ELECTRODE, SINGLE	8900-0402	45806
STAT-PADZ II ELECTRODE, SINGLE	8900-0801-01	45806
PEDI-PADZ II ELECTRODES - ONE PAIR	8900-0810-01	42404
ONESTEP BASIC ELECTRODES WITH GREEN CONNECTOR	8900-000250-05	45806
ONESTEP CPR A/A ELECTRODES WITH GREEN CONNECTOR	8900-000251-05	45806
ONESTEP PEDIATRIC ELECTRODES WITH GREEN CONNECTOR	8900-000252-05	42404
Battery Accessories		
ZOLL AED 3 BATTERY PACK	8000-000696	48058
ZOLL AED 3 AVIATION BATTERY PACK	8000-000697	48058
Non-medical device accessories		
CPR UNI-PADZ TRAINING KIT	8900-000264	
CPR UNI-PADZ, II TRAINING KIT	8900-000274	
CPR UNI-PADZ, III TRAINING KIT	8900-000284	
AED PLUS 2 CARRY CASE	8000-001250	
POUCH, BATTERY, ZOLL AED 3	8000-001251	
SHOULDER STRAP, CARRY CASE, ZOLL AED 3	8000-001252	
SMALL RIGID PLASTIC CARRY CASE, ZOLL AED 3	8000-001253	
LARGE RIGID PLASTIC CARRY CASE, ZOLL AED 3	8000-001254	

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

BRACKET, WALL MOUNT, ZOLL AED 3	8000-001255
WALL CABINET, STANDARD SURFACE, ZOLL AED 3	8000-001256
WALL CABINET, SEMI-RECESSED, ZOLL AED 3	8000-001257
WALL CABINET, FULLY-RECESSED, ZOLL AED 3	8000-001258
STROBE LIGHT, AED PLUS SERIES	8000-001259
ILCOR FLUSH WALL SIGN (AED)	8000-001260
ILCOR 3-D WALL SIGN (AED)	8000-001261
ILCOR FLUSH WALL SIGN (DAE)	8000-001262
ILCOR 3-D WALL SIGN (DAE)	8000-001263
ILCOR FLUSH WALL SIGN (DEA)	8000-001264
ILCOR 3-D WALL SIGN (DEA)	8000-001265
BRACKET, WALL MOUNT, CASE, ZOLL AED 3	8000-001266
STROBE LIGHT W/PLATE, AED PLUS SERIES	8000-001267
ZOLL AED SIMULATOR	8000-000925
SOFT CARRY CASE, ZOLL AED 3	8000-001280

Authorised signatory:

Signature

Name: Elizabeth Haines
Position: Director, Regulatory Affairs
Location: Chelmsford, MA USA

March 29, 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



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
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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

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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