

Specificatia tehnică completată

Model: ZOLL M2 Producător: ZOLL Medical+Suzhou ZOLL Medical; Tara: SUA si China

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către autoritatea ofertantă
Defibrilator extern, manual (caracteristici de bază) Descriere Defibrilator extern, manual destinat utilizării personalului specializat cu caracteristici de bază Parametrul Specificația Defibrilator Selectarea energiei "adult 50-360 bifazic; 2-20 pediatric/nou-născut" Controlul padelelor Încărcare da descărcarea energiei da Forma de undă la ieșire bifazic Sincronizator da Display Afișarea derivațiilor bipolare I, II, III Captarea semnalului ECG prin intermediul padelelor da Afișarea ritmului cardiac da Alarmer ale ritmului cardiac da Frecvența de lucru 0.67-40 Hz Indicator al devierii derivațiilor cardiace da Modul ECG Captarea semnalului ECG prin fir cu 3 electrozi da Diapazon 30 - 300 BPM Protecție în potruva șocurilor de defibrilare ≥ 360 J Mesaje de alarmă da Imprimantă pentru ECG Viteza hîrtiei 12.5, 25, 50 mm/sec Imprimantă termică încorporată da Printare auto sau manuală Adnotări ora da data da derivația da ritmul cardiac da modul de operare da forma unde descărcate da Funcția sumară da Memorie Memorie internă sau Posibilitatea de instalarea a cartelei de memorie da Informația stocată ECG, șoc, vocele din anturaj Capacitatea de stocare ≥ 2 ore Alimentarea Rețea electrică 220 V, 50 Hz da Baterie internă reîncărcabilă da	Defibrilator extern, manual (caracteristici de bază) Descriere Defibrilator extern, manual destinat utilizării personalului specializat cu caracteristici de bază DA Parametrul Specificația Defibrilator Selectarea energiei "adult 1 - 200 bifazic rectiliniu; 1-20 pediatric/nou-născut" DA Controlul padelelor Încărcare DA descărcarea energiei DA Forma de undă la ieșire bifazic rectiliniu DA Sincronizator DA Display Afișarea derivațiilor bipolare I, II, III DA Captarea semnalului ECG prin intermediul padelelor DA Afișarea ritmului cardiac DA Alarmer ale ritmului cardiac DA Frecvența de lucru 0.67-40 Hz DA Indicator al devierii derivațiilor cardiace DA Modul ECG Captarea semnalului ECG prin fir cu 3 electrozi DA Diapazon 20 - 300 BPM DA Protecție în potruva șocurilor de defibrilare - 360 J DA Mesaje de alarmă DA Imprimantă pentru ECG Viteza hîrtiei 25, 50 mm/sec DA Imprimantă termică încorporată DA Printare auto sau manuală DA Adnotări ora DA data DA derivația DA ritmul cardiac DA modul de operare DA forma unde descărcate DA Funcția sumară DA Memorie Memorie internă sau Posibilitatea de instalarea a cartelei de memorie DA Informația stocată ECG, șoc, vocele din anturaj DA Capacitatea de stocare ≥ 2 ore Alimentarea Rețea electrică 220 V, 50 Hz da Baterie internă reîncărcabilă da

Timp de lucru de la baterie 3 ore ECG continuu sau min. 100 descărcări la energia maximă Greutatea cu accesorii < 9 kg Accesorii Padele Adult, reutilizabile 1 set. "Pediatrice, reutilizabile (padele sau adaptoare pediatrice)" 1 set. Cablu ECG reutilizabil 3 fire 1 buc. Electrozi ECG Adult, unică utilizare, cu termenul de valabilitate 2 ani la momentul livrării 50 buc . Hîrtie termică 5 buc. Gel de contact 250 ml Cantitatea necesara 2 buc.	Timp de lucru de la baterie 4 ore ECG continuu sau min. 100 descărcări la energia maximă DA Greutatea cu accesorii - 6.5 kg DA Accesorii Padele Adult, reutilizabile 1 set. DA "Pediatrice, reutilizabile (adaptoare pediatrice)" 1 set. DA Cablu ECG reutilizabil 3 fire 1 buc. DA Electrozi ECG Adult, unică utilizare, cu termenul de valabilitate 2 ani la momentul livrării 50 buc. DA Hîrtie termică 5 buc. DA Gel de contact 250 ml DA Cantitatea necesara 2 buc. DA
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ZOLL M2™

Технические характеристики



Дефибриллятор-монитор ZOLL M2™ разработан с использованием надежных технологий ZOLL® и обеспечивает оптимальное выполнение задач от мониторинга пациентов высокого риска до реанимационных мероприятий с высоким качеством СЛР.

Больше поддержки

ZOLL M2 поможет вам качественно реанимировать взрослых и детей благодаря наличию ряда функций, помогающих спасти жизни, в том числе функции контроля качества СЛР, кардиоверсии и кардиостимуляции, а также режима АНД для взрослых и детей.

Больше надежных технологий

ZOLL M2 соответствует проверенному портфолио реанимационной продукции компании ZOLL, которая предназначена для непрерывной и высококачественной СЛР и выполнения дефибрилляции с высокой силой тока детям и взрослым.

Больше добавочной ценности

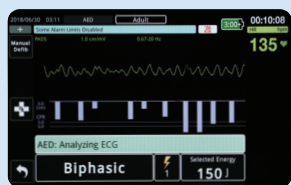
ZOLL M2 разработан для стационаров и скорой медицинской помощи, включает лучшие в своем классе технологии и позволяет оказывать пациентам качественную помощь – при сниженных эксплуатационных затратах.

Лучшая масштабируемость*

Возможности ZOLL M2 позволяют выполнять задачи от простейшей дефибрилляции до самых сложных клинических случаев с использованием различных вариантов комплектации, в том числе мониторинга ЭКГ в 12 отведениях*, EtCO2*, НИАД*, SpO2*, температуры (2 канала)*.

*Эта функция будет доступна в будущих модификациях.

ZOLL®



Прямоугольный бифазный импульс дефибрилляции

Доказано, что разработанная в компании ZOLL форма импульса наиболее эффективна для дефибрилляции пациентов с высоким импедансом.



Контроль качества СЛР

Разработанная в компании ZOLL функция контроля качества СЛА применяется клиницистами во всем мире для достижения высокого качества СЛР.



Патентованная форма импульса дефибрилляции продолжительностью 40 мс

Разработанный в компании ZOLL патентованный импульс кардиостимуляции длительностью 40 мс обеспечивает высочайшую результативность на вызывании ритма при самой низкой средней силе тока, необходимой для эффективности и комфорта пациента.



Многоразовые клейкие электроды для hands-free дефибрилляции

Надежная технология компании ZOLL приходит на замену обычным наружным электродам и позволяет безопасно выполнять дефибрилляцию, опираясь на функцию Real CPR Help®.

Чтобы больше узнать о ZOLL M2, пройдите по ссылке info.zoll.com/m2

ZOLL Medical Corporation
Центральный международный офис
269 Mill Road
Chelmsford, MA 01824, USA (США)
978-421-9655
800-804-4356

Для поиска адресов и номеров факса, а также других филиалов компании по всему миру перейдите по адресу www.zoll.com/contacts.

Технические характеристики ZOLL M2™

Общие

Размер: Без рукоятки: 264,7 x 231,3 x 223,6 мм; с рукояткой: 264,7 x 231,3 x 274,6 мм

Масса: 5,9 без батареи и бумаги; 6,5 кг с батареей и бумагой

Источники питания: Сеть переменного тока: 100-240 В, 50/60 Гц, 200 ВА; батарея: блок литиевых аккумуляторных батарей.

Индикатор низкого заряда батареи: Если оставшегося заряда батареи хватит менее чем на 30 минут мониторинга ЭКГ, на экране появляется сообщение «НИЗКИЙ ЗАРЯД БАТАРЕИ»

Стандарты проектирования: Соответствует или превышает соответствующие требования стандартов EN 60601-1, EN 60601-2-4, EN 60601-2-27, EN 1789

Безопасность пациента: Все подключаемые к пациенту элементы снабжены электрической изоляцией

Параметры среды

Влажность: относительная – 5-95% (без конденсации)

Вибрация: EN ISO 80601-2-61 (согласно IEC 60068-2-64), EN 1789 для санитарных автомобилей

Разряд: IEC 60068-2-27, 100 г, 6 мс полусинусоидальный

Удар: IEC 60068-2-29

Атмосферное давление: 620-1060 мбар (от -381 до 4000 м)

Температура: 0-50°С

Свободное падение: EN 1789, функциональное падение 0,75 м

Хранение и транспортировка: Температура: от -30 до 70°С, влажность: относительная – 5-95% (без конденсации), сотрясение/вибрация: ISTA 2A

Классификация по безопасности: Класс I, внутренний источник питания соответствует EN/IEC 60601-1

Защита корпуса (EN/IEC 60529): Попадание внутрь частиц и воды: IP44

Дефибриллятор

Форма импульса: Rectilinear Biphasic™

Диапазон импеданса пациента: от 15 до 300 Ом

Варианты выбора энергии: от 1 до 10, 15, 20, 30, 50, 70, 85, 100, 120, 150, 200 Дж, устанавливается посредством элементов управления на передней панели дефибриллятора или на стерильном утюжковом электроде

Уровни интеллектуального выбора энергии: Автоматическое повышение уровня энергии согласно установленному протоколу для взрослых или детей

Отображение уровня энергии: Установленный уровень энергии и энергия поданного разряда выводятся на монитор

Время зарядки: От новой и полностью заряженной батареи – менее 7 секунд (первые 15 разрядов до 200 Дж); если батарея разряжена или не нова, зарядка может занимать больше времени.

Синхронизированный режим: Синхронизация разряда дефибрилляции с зубцом R пациента. На экране отображается надпись «SYNC», а зубцы R отмечаются маркерами над ЭКГ на экране и на бумажной ленте. Разряд дефибриллятора менее чем через 60 мс после вершины зубца R.

Управление зарядкой: Элементы управления на передней панели

дефибриллятора или на верхушечном ручном электроде

Утюжковые электроды: Наружные стерильные/верхушечные утюжковые электроды; пластины для взрослых снимаются, открывая поверхность пластин для детей.

Мониторинг ЭКГ

Подключение к пациенту: кабель для ЭКГ в 3 отведениях, кабель для ЭКГ в 5 отведениях, ручные электроды, многофункциональные электроды

Защита входной линии: Полная защита от разряда дефибриллятора. Электрические схемы исключают искажение сигнала ЭКГ под действием импульсов кардиостимуляции

Отображение импульсов имплантированного кардиостимулятора: Электрические схемы рассчитаны на определение импульсов большинства имплантируемых кардиостимуляторов с обозначением маркером на ЭКГ

Частотная полоса: Наклеиваемые/ручные электроды: 0,67-20 Гц или 0,67-40 Гц (регулируется)

Мониторинг в 3/5 отведениях (регулируется): 0,67-20 Гц или 0,67-40 Гц (регулируется)

0,525-40 Гц Диагностический режим
Выбор отведений: Утюжковые (наклеиваемые) электроды, I, II, III, aVR, aVL, aVF, V

Масштаб ЭКГ: 0,125; 0,25; 0,5; 1,0; 1,5; 2,0; 3,0 см/мВ или автоматически

Отображение частоты сердечных сокращений: 0, 20-300 уд./мин.

Тревога по частоте сердечных сокращений: По выбору пользователя

CPR Dashboard™ с функцией Real CPR Help®

включается при подключении электродов ZOLL для СЛР.

Технология измерения: Акселерометрическая

Глубина нажатий: Определяется в диапазоне от 1,9 см до 7,6 см, с точностью ±0,6 см

Частота нажатий: Определяется в диапазоне от 50 до 150 нажатий в минуту

Контроль качества СЛР: Настраиваемые звуковые и визуальные указания относительно частоты и глубины нажатий, если нажатия выполняются не в соответствии с рекомендациями AHA/ERC.

Экран

Тип экрана: Цветной LCD, 800X480 пикселей.

Размер экрана: диагональ 17,8 см/7,0 дюйма

Скорость развертки: 12,5 мм/с, 25 мм/с, 50 мм/с (по выбору пользователя)

Каналы: 4

Информация: Частота сердечных сокращений, отведения/электроды, включение/отключение тревоги, выбранный уровень энергии, энергия поданного разряда, рекомендации и предупреждения для пользователя, SpO₂*, NIAД*, EtCO₂*, функции кардиостимулятора, маркеры кодов, панель управления СЛР

Блоки батарей

Тип: аккумуляторные, литиевые, 10,8 В (номинальное напряжение)

Емкость: 5,8 ампер-часов

Масса: 0,77 кг

Время перезарядки: 100% за 5 часов

Время работы: Не менее 4 часов непрерывного мониторинга ЭКГ и 20 разрядов дефибрилляции энергией 200 Дж; 100 разрядов дефибрилляции максимальной энергией (200 Дж); 3,5 часов мониторинга ЭКГ и кардиостимуляции с частотой 180 имп./мин. и током 140 мА.

Технология печати

Матричный термопринтер высокого разрешения, ширина бумаги 80 мм

Скорость: 25 мм/с, 50 мм/с, задержка 6 секунд

Режимы печати: Вручную и автоматически (по выбору пользователя)

Аннотации: Время, дата, отведение ЭКГ, усиление ЭКГ, частотная характеристика ЭКГ, частота сердечных сокращений, параметры дефибрилляции и кардиостимуляции, обзор лечебных процедур

Обмен данными

USB: 1

Поддержка WiFi: 802.11 a/b/d/e/g/h/i/n

АНД

Функция рекомендации разряда: Выполняется оценка ритма на ЭКГ и определение показаний к разряду дефибрилляции

Подлежащие дефибрилляции ритмы: Фибрилляция желудочков с амплитудой >100 мкВ, а также желудочковая тахикардия с широкими комплексами с частотой >150 уд./мин. у взрослых или >200 уд./мин. у детей. Подробные сведения о чувствительности и специфичности приведены в руководстве оператора.

Настройка протоколов: Возможна настройка протоколов, предусматривающих первоначальное проведение СЛР или выполнение дефибрилляции. Можно также настроить энергию одного разряда или последовательности разрядов – неизменную или возрастающую. Продолжительность СЛР в промежутках настраивается в пределах до 4 минут с шагом в 1 минуту.

Наружная кардиостимуляция

Тип: Наружная чрескожная кардиостимуляция, VVI по требованию или асинхронно (с фиксированной частотой)

Импульс: Прямоугольной формы, постоянный ток

Ширина импульса: 40 мс ± 2 мс

Частота импульсов кардиостимуляции: 30-180 уд./мин. ± 2 уд./мин

Выходное напряжение: 0 - 140 мА ± 5% но не менее чем 5 мА

Защита выходной линии: Полная защита от разряда дефибриллятора и изоляция

Пульсоксиметрия (SpO2)

Диапазон сатурации: 0% - 100%, разрешающая способность 1%

Диапазон частоты пульса: 25 - 240 уд./мин., разрешающая способность 1 уд./мин.

Точность измерения сатурации: В диапазоне 70 - 100: ± 2% для взрослых/детей

Точность измерения частоты пульса: ± 3% величины показателя, но не менее чем 2 уд./мин., для взрослых/детей

Технические характеристики могут быть изменены без уведомления.

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Напечатано в США. MCN IP 1911 0296-29

ZOLL®

The Commonwealth of Massachusetts

William Francis Galvin
Secretary of the Commonwealth

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: United States of America

This public document

2. has been signed by: Rebecca M. Davis

3. acting in the capacity of: Notary Public

4. bears the seal/stamp of: Rebecca M. Davis

whose commission expires on: June 5, 2026

Certified

5. at: Boston, Massachusetts

6. the: 26 February, 2020

7. by: the Secretary of the Commonwealth

8. No.: 2194806

9. Seal/stamp:

Great Seal of the Commonwealth

10. Signature:



William Francis Galvin
Secretary of the Commonwealth





269 Mill Road
Chelmsford, Massachusetts 01824-4111

978.421.9655 (main)

978.421.0025 (fax)

www.zoll.com

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Certify a Copy:

Commonwealth of Massachusetts

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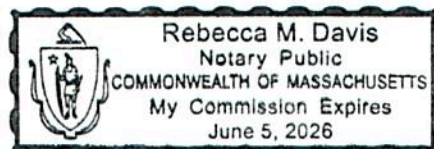
On this 21 day of February, 2020, I certify that the preceding or attached document, is a true, exact, complete, and unaltered copy made by me Rebecca Davis, presented to me by the document's custodian, Joline Palasek, and that, to the best of my knowledge, the photocopied document is neither a public record nor a publicly recordable document, certified copies of which are available from an official source other than a notary.

- EC Certificate ZOLL Suzhou

A handwritten signature in black ink, appearing to read "Rebecca Davis", is written over a horizontal line.

Rebecca Davis
Notary Public Signature

Notary Stamp



Notary Seal



Certificate

No. Q5 103242 0001 Rev. 00

Holder of Certificate: Suzhou ZOLL Medical Technology Co., Ltd.

Room102-2, Block 19, No.8 Jinfeng Road
Suzhou New District
215163 Suzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Suzhou ZOLL Medical Technology Co., Ltd.
Room102-2, Block 19, No.8 Jinfeng Road, Suzhou New District,
215163 Suzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development,
Production, Distribution
and Servicing of
Defibrillator / Monitor

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH19143401

Valid from: 2019-06-28

Valid until: 2022-03-31

Date, 2019-06-28

S. Pennip

Stefan Preiß

Head of Certification/Notified Body

The Commonwealth of Massachusetts

William Francis Galvin
Secretary of the Commonwealth

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Great Seal of the Commonwealth

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William Francis Galvin

William Francis Galvin
Secretary of the Commonwealth





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Certify a Copy:

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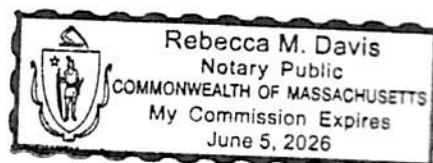
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- Declaration of Conformity- ZOLL M2

A handwritten signature in black ink, appearing to read 'Rebecca Davis', is written over a horizontal line.

Rebecca Davis
Notary Public Signature

Notary Stamp



Notary Seal



Declaration of Conformity



Suzhou ZOLL Medical Technology Co., Ltd.
Room102-2, Block 19, No.8 Jinfeng Road
Suzhou New District, 215163 Suzhou
Jiangsu, P.R. China



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

Product: ZOLL M2 Monitor/Defibrillator
UMDNS/GMDN Code: 37806
Classification (MDD, Annex IX): IIb, rule 9
Conformity Assessment Route: Annex II.3

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC), amended by DIRECTIVE 2007/47/EC.

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstr. 65, 80339 MÜNchen, Germany
Identification number: CE0123
(EC) Certificate(s): G1 103242 0002
Expire date of the Certificate: 2024-05-26
Start of CE Marking: 2019-07-25
Place, Date of Issue: Suzhou, 2019-07-25

Signature:

Name:

Anna Zhu

Title: Sr. QA/RA Manager



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**

Therapy Electrodes	
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
Battery	
TYPE 123 LITHIUM BATTERIES	8000-0807-01
AED Plus Trainer	
AED Plus Trainer 2	8008-0050-XX
AED Plus Fully Automatic Trainer 2	8008-000052-XX
Other Accessories	
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
Non-Medical Device Accessories	
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
Therapy Electrodes		
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
Battery		
TYPE 123 LITHIUM BATTERIES	8000-0807-01	35848

Non-Medical Device Accessories	
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



**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 13968-9-2020

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Two Pages)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from September 10, 2020 to September 09, 2022.





U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 13968-9-2020

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Manufactured for Owner Operator

ZOLL MEDICAL CORPORATION
269 MILL ROAD
Chelmsford, MA USA 01824

Name of Manufacturer

ZOLL MEDICAL CORPORATION
269 MILL ROAD
CHELMSFORD, MA USA 01824

BIO-DETEK, INC.
525 Narragansett Park Dr
PAWTUCKET, RI USA 02861

Name of Distributor

ZOLL MEDICAL CORPORATION
269 MILL ROAD
CHELMSFORD, MA USA 01824

---END OF MANUFACTURER/DISTRIBUTOR LIST----





Certificate No. 13968-9-2020

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2

Manufactured for Owner Operator

ZOLL MEDICAL CORPORATION
269 MILL ROAD
Chelmsford, MA USA 01824

Name of Manufacturer

ZOLL MEDICAL CORPORATION
269 MILL ROAD
CHELMSFORD, MA USA 01824

BIO-DETEK, INC.
525 Narragansett Park Dr
PAWTUCKET, RI USA 02861

Name of Distributor

ZOLL MEDICAL CORPORATION
269 MILL ROAD
CHELMSFORD, MA USA 01824

Name of Product(s)

ZOLL X Series Advanced
ZOLL AED 3
ZOLL AED 3 with Uni-padz
ZOLL AED 3 BLS Defibrillator
ZOLL D1400 Defibrillator
ZOLL PD1400 Pacemaker/Defibrillator
ZOLL 1600 Defibrillator
ZOLL 1700 Defibrillator
ZOLL D2000 Defibrillator
ZOLL PD2000 Pacemaker/Defibrillator
ZOLL M Series Defibrillator
ZOLL M Series with Rectilinear Bi-Phasic Option
ZOLL M Series SPO2 Option
ZOLL M Series 12SL Analysis Option
ZOLL M Series ETCO2 Option
ZOLL M Series NIBP Option
ZOLL M Series CCT with IBP Temperature Option
ZOLL E Series Defibrillator
ZOLL E Series with Real CPR Help
ZOLL E Series with See-Thru CPR
ZOLL E Series 12SL, Analysis Option
ZOLL E Series with Intubation Assist Option
ZOLL E Series with Bluetooth Dial Up Networking
ZOLL E Series with SPCO/SPMET Option
ZOLL E Series with CPR Ready Charge
ZOLL R Series Defibrillator
ZOLL R Series BLS Defibrillator
ZOLL R Series with NIBP and ETCO2 Options
ZOLL X Series Defibrillator
ZOLL AED Plus Defibrillator
ZOLL Fully Automatic AED Plus Defibrillator
ZOLL AED Pro Defibrillator
ZOLL Propaq MD DC Defibrillator (incl. paddles)
ZOLL Propaq M Cardiac Monitor
ZOLL One Step Electrodes
ZOLL One Step Basic Electrodes
ZOLL One Step Pacing Electrodes
ZOLL One Step CPR Electrodes





Certificate No. 13968-9-2020

Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 2

ZOLL One Step CPR (AA) Electrodes
ZOLL One Step Complete Electrodes
ZOLL One Step Pediatric Electrodes
ZOLL OneStep CPR II MFE Adult Multi-Function Electrode
ZOLL OneStep CPR Pediatric Multi-Function Electrode
ZOLL Radiolucent Solid Gel Electrodes
ZOLL Radiolucent Liquid Gel Electrodes
ZOLL Pro Padz Sterile Electrodes
ZOLL Pro Padz Bi-Phasic Electrodes
ZOLL Pedi Padz Solid Gel Electrodes
ZOLL Pedi Padz Radiolucent Electrodes
ZOLL Pedi Padz Pediatric Electrodes
ZOLL Pedi Padz II Electrodes
ZOLL Stat Padz Adult Multi-Function Electrodes
ZOLL Stat Padz II Electrodes
ZOLL CPR Stat Padz Electrodes
ZOLL Dura Padz Reusable Electrodes
ZOLL Dura Padz Gel Disposable Hydrogel
ZOLL CPR Dura-Padz Reusable Defibrillation Electrode with Dura-Padz Gel
ZOLL Pro Padz Electrodes
ZOLL Ready Padz Multi-Function Electrodes
ZOLL CPR-D Padz Electrodes
ZOLL PD2200 Multi-Function Electrodes
ZOLL Cardiology Specialty Electrodes
ZOLL Autoclavable Internal Handles Paddles
ZOLL Base PowerCharger 4x4 Battery Charger/Tester
ZOLL PowerCharger AC Power/Charge Module
ZOLL SurePower Charger Single bay charger
ZOLL Power Infuser Infusion Pump with Cartridges (M100B-3A)
ZOLL RescueNet Link Software-only product
ZOLL RescueNet 12-Lead Software-only product
ZOLL RescueNet ePCR Software-only product
ZOLL ePCR iOS Software-only product
ZOLL Code Writer Software-only product
ZOLL PocketCPR Cardiopulmonary Resuscitation Aid
731 Series Ventilators Model EMV, EMV+ (and EMV+ MRI), Eagle II (and Eagle II MRI),
AEV Continuous Ventilator, Z Vent, Z Vent MRI, and Z Vent Basic
Model 326/326M Aspirator, Model 324/324K Portable Aspirator
Model 330 Multifunction Aspirator

-----END OF PRODUCT LIST-----





Certificate

No. Q5 079546 0024 Rev. 00

Holder of Certificate: **ZOLL Medical Corporation**

269 Mill Road
Chelmsford MA 01824-4105
USA

Certification Mark:



Scope of Certificate: **Design and Development, Production, and Servicing of Defibrillators, External Pacemakers, Multi-parameter Monitoring System, Adapters, Cables, Leads, Electrodes, Probes, Sensors, Blood Cartridge and Crystalloid/Colloid Cartridge, Portable Ventilators with Patient Breathing Circuits, Stand Alone Medical Software for the areas of Cardiac Resuscitation, Impedance Threshold Devices, Critical Care and Vital Signs Monitoring, and Aspirators.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 079546 0024 Rev. 00

Report No.: 72155739

Valid from: 2020-09-22

Valid until: 2021-06-01

Date, 2020-09-22

Christoph Dicks

Head of Certification/Notified Body

Certificate

No. Q5 079546 0024 Rev. 00

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): ZOLL Medical Corporation
269 Mill Road, Chelmsford MA 01824-4105, USA

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

Parameters:



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
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

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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