


Declaration of Conformity

 **ZOLL Medical Corporation**
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ZOLL Medical Switzerland AG
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We herewith declare that the products detailed within this declaration meet the requirements and provisions of the EU Medical Device Regulation 2017/745 and Switzerland's Medical Device Ordinance (MedDO) of 1 July 2020. All supporting documentation is retained on the premises of ZOLL Medical Corporation. ZOLL Medical Corporation assumes responsibility for compliance with the requirements of Regulation (EU) 2017/745, MedDO, and all other Union legislation applicable to the device.

The products detailed within this declaration 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provisions of Council Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment which was repealed by Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on Waste Electrical and Electronic Equipment (WEEE).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, these products are in conformance with the provisions of Directive 2012/19/EU.

In addition, the products listed herein are in conformance with the provisions of Council Directive 2011/65/EU as amended on the restriction of the use of certain hazardous substances in electrical and electronic equipment which apply to them.

SRN	US-MF-000021386 – Manufacturer NL-AR-000012554 – EU Rep
Basic UDI-DI	08479460RTF
EU Quality Management System Certificate	<p><u>Certificate #:</u> G12 079546 0032</p> <p><u>Annex</u> Annex IX Chapters I and III</p> <p><u>Valid From:</u> 13-02-2024</p> <p><u>Valid Until</u> 12-02-2029</p> <p>TÜV SÜD Product Service GmbH Zertifizierstelle, Ridlerstraße 65, 80339 München Germany</p>

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	Notified Body Identification #0123
EC Certificate Details	<u>Certificate #:</u> G70 079546 0031 <u>Annex:</u> Annex IX, Chapter II <u>Valid From:</u> 19-09-2024 <u>Valid Until</u> 18-09-2029 TÜV SÜD Product Service GmbH Zertifizierstelle, Ridlerstraße 65, 80339 München Germany Notified Body Identification #0123
Devices:	See Attachment 1
Risk Class, Rule	Class III, Rule 22
Intended Purpose	The intended purpose of the ZOLL AED Plus is to help victims of sudden cardiac arrest. Using compatible ZOLL defibrillation electrodes which connect the patient to the ZOLL AED Plus, the AED automatically analyzes the victim's ECG rhythm to determine whether an electrical shock should be delivered. If the AED detects a shockable rhythm (coarse ventricular fibrillation or wide complex ventricular tachycardia), it alerts the rescuer that a shock is advised and then it either issues instructions to press the flashing shock button (semi-automatic model) or it automatically delivers the shock after a 3 second countdown (fully automatic model). The AED then prompts the rescuer to perform CPR for a pre-conditioned period of time.
Harmonized Standards	See "General Safety and Performance Requirements Checklist"
Common Specifications	N/A

For and on behalf of
ZOLL Medical Corporation

Name: Natalie England
Position: Director, Regulatory Affairs
Location: Chelmsford, MA 01824-4105 USA

Date:

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Attachment 1:

REF	UDI	Description
20000000100011020	00847946031374	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, French
20000000100011100	00847946024239	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Spanish
20000000300011070	00847946031657	MAIN ASSY, PS Series, No Graphics, LCD, No Voice RCDG, 50HZ, UK
20000000100011050	00847946031398	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, UK
20000000100011080	00847946031411	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, German
20000000100011110	00847946031435	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Italian
20000000100011160	00847946031459	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Dutch
20000000100011180	00847946031473	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Portuguese
20000000100011210	00847946031503	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Finnish
20000000100011010	00847946002152	MAIN ASSY, PS Series, LCD, No Voice RCDG, English
20000000100011070	00847946031404	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, UK (Proper)
20000000100011090	00847946031428	MAIN ASSY, PS Series, LCD, No Voice RCDG, AHA, Switzerland/German
20000000100011410	00847946031305	MAIN ASSY, PS Series, LCD, No Voice RCDG, AHA, Switzerland/Italian
20000000100011550	00847946031596	MAIN ASSY, PS Series, LCD, No Voice RCDG, Turkish, 50HZ
20000000300011050	00847946031640	MAIN ASSY, PS Series, No Graphics, LCD, No Voice RCDG, 50HZ, UK
20000001100011100	00847946031800	MAIN ASSY, PS Series, LCD, Voice RCDG, Spanish
20000001100011020	00847946031763	MAIN ASSY, PS Series, LCD, Voice RCDG, French
20000001300011410	00847946032081	MAIN ASSY, PS Series, No Graphics, LCD, Voice RCDG, AHA, Switzerland/Italian
20000800100011050	00847946032265	MAIN ASSY, PS Series, ECG On, LCD, No Voice RCDG, 50HZ, UK
20000800100011080	00847946032272	MAIN ASSY, PS Series, ECG On, LCD, No Voice RCDG, German
20000800100011110	00847946032289	MAIN ASSY, PS Series, ECG On, LCD, No Voice RCDG, Italian
20000800100011410	00847946032302	MAIN ASSY, PS Series, ECG On, LCD, No Voice RCDG, Italian
20000800300011070	00847946032340	MAIN ASSY, PS Series, No Graphics, ECG On, LCD, No Voice RCDG, UK (Proper)
20000000100011040	00847946031381	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Polish
20000000100011170	00847946031466	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Czech
20000000100011200	00847946031497	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, NORWEGIAN
20000000100011220	00847946031510	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Swedish
20000000100011270	00847946031534	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Danish
20000000100011290	00847946031558	MAIN ASSY, PS Series, LCD, No Voice RCDG, ERC, Russian
20000000100011340	00847946031275	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Arabic
20000000100011450	00847946031336	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, HUNGARIAN
20000000100011520	00847946031565	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Croatian
20000000100011530	00847946031572	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Slovenian
20000000100011130	00847946023621	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, AUS
20000000100011190	00847946031480	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Greek
20000000100011330	00847946031268	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Thai
20000000100019050	00847946031619	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Airline, UK
20000000100019080	00847946031626	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Airline, German
20000000300011020	00847946031633	MAIN ASSY, PS Series, No Graphics, LCD, No Voice RCDG, 50HZ, French
20000000300011080	00847946031664	MAIN ASSY, PS Series, No Graphics, LCD, No Voice RCDG, 50HZ, German
20000000300011160	00847946031695	MAIN ASSY, AED Plus, PS Series, No Graphics, LCD, No Voice RCDG, Dutch
20000000300011210	00847946031701	MAIN ASSY, AED Plus, PS Series, No Graphics, LCD, No Voice RCDG, Finnish
20000001100011050	00847946031770	MAIN ASSY, PS Series, LCD, Voice RCDG, 50HZ, UK
20000001100011080	00847946031787	MAIN ASSY, PS Series, LCD, Voice RCDG, German

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20000001100011110	00847946031817	MAIN ASSY, PS Series, LCD, Voice RCDG, Italian
20000001100011170	00847946031848	MAIN ASSY, PS Series, LCD, Voice RCDG, Czech, 50HZ
20000001100011180	00847946031855	MAIN ASSY, PS Series, LCD, Voice RCDG, Portuguese, 50HZ
20000001100011290	00847946031916	MAIN ASSY, PS Series, LCD, Voice RCDG, ERC, Russian
20000001100011530	00847946031978	MAIN ASSY, PS Series, LCD, Voice RCDG, Slovenian, 50HZ
20000001100011410	00847946031947	MAIN ASSY, PS Series, LCD, Voice RCDG, AHA, Switzerland/Italian
20000001300011020	00847946032012	MAIN ASSY, AED Plus, PS Series, No Graphics, LCD, Voice RCDG, French
20000001300011110	00847946032036	MAIN ASSY, PS Series, No Graphics, LCD, Voice RCDG, 50HZ, Italian
20000800101011290	00847946032333	MAIN ASSY, PS Series, ECG On, LCD, No Voice RCDG, Russian
20000800100011040	00847946032258	MAIN ASSY, PS Series, ECG On, LCD, No Voice RCDG, 50HZ, Polish
20000800100019080	00847946032326	MAIN ASSY, PS Series, ECG On, LCD, No Voice RCDG, 50HZ, Airline, German
20000800300011080	00847946032357	MAIN ASSY, PS Series, ECG On, LCD, No Voice RCDG, 50HZ, German
20000000000000020	00847946031183	MAIN ASSY, PA Series, No LCD, No Voice RCDG, French
20000000000000080	00847946031190	MAIN ASSY, PA Series, No LCD, No Voice RCDG, German
20000000000000160	00847946031213	MAIN ASSY, PA Series, No LCD, No Voice RCDG, Dutch
20000000000000180	00847946031220	MAIN ASSY, PA Series, No LCD, No Voice RCDG, Portuguese
2000060300011070	00847946032111	MAIN ASSY, PS Series, LCD, No Voice RCDG, UK English, Aviation
20000000100011260	00847946024222	MAIN ASSY, PS Series, LCD, No Voice RCDG, 60HZ, French
20000000100011590	00847946029203	MAIN ASSY, PS Series, LCD, No Voice RCDG, Singapore
20000000300011010	00847946002169	MAIN ASSY, PS Series, No Graphics, LCD, No Voice RCDG, English
20000000300011260	00847946031732	MAIN ASSY, PS Series, No Graphics, LCD, No Voice RCDG, 50HZ, French, Canadian
20000001100011010	00847946002183	MAIN ASSY, PS Series, LCD, Voice , RCDG, English
20000001100011590	00847946029210	MAIN ASSY, PS Series, LCD, Voice , RCDG, Singapore
20000001100011260	00847946031909	MAIN ASSY, PS Series, LCD, Voice RCDG, 60HZ, French
20000001300011010	00847946002190	MAIN ASSY, PS Series, No Graphics, LCD, Voice RCDG, English
20000001300011260	00847946032074	MAIN ASSY, AED Plus, PS Series, No Graphics, LCD, Voice RCDG, French/ Canadian
20000100200000010	00847946002213	MAIN ASSY, PA Series, No GRAPH, No CPR, No LCD, No Voice RCDG, English
20000101200000010	00847946002220	MAIN ASSY, PA Series, No Graphics, No LCD, Voice RCDG, English
20000800100011010	00847946002244	MAIN ASSY, PS Series, ECG On, LCD, No Voice RCDG, English
20000800300011010	00847946002251	MAIN ASSY, PS Series, No Graphics, ECG On, LCD, No Voice RCDG, English
20000000100011140	00847946028862	MAIN ASSY, PS Series, LCD, No Voice RCDG, 60HZ, Korea
20000001100011140	00847946028886	MAIN ASSY, PS Series, LCD, Voice RCDG, Korean, 60HZ
20000801100011140	00847946032371	MAIN ASSY, PS Series, ECG On, LCD, Voice RCDG, Korean, 60HZ
20000000000000010	00847946002145	MAIN ASSY, PA Series, No LCD, No Voice RCDG, English
20000000321012010	00847946002176	MAIN ASSY, PS Series, No Graphics, LCD, No Voice RCDG, English
2000060100011010	00847946017088	MAIN ASSY, PS Series, LCD, No Voice RCDG, English, Aviation
20000800100011020	00847946032241	MAIN ASSY, PS Series, ECG On, LCD, No Voice RCDG, French
20000001100011550	00847946031992	MAIN ASSY, PS Series W/Basic CVR, LCD, Voice RCDG, 50HZ, Turkish
20000800100011580	00847946032319	MAIN ASSY, PS Series, ECG On, LCD, No Voice RCDG, 50HZ, NEW ZEALAND
20000000000000050	00847946031206	MAIN ASSY, PA Series, No LCD, No Voice RCDG, UK
20000001300011080	00847946032029	MAIN ASSY, AED Plus, PS Series, No Graphics, LCD, Voice RCDG, German
20000001100011090	00847946031794	MAIN ASSY, PS Series, LCD, Voice RCDG, AHA, Switzerland/German
20000000300011100	00847946031671	MAIN ASSY, PS Series, No Graphics, LCD, No Voice RCDG, 50HZ, Spanish
20000000000000100	00847946031237	MAIN ASSY, PA Series, No LCD, No Voice RCDG, Spanish
20000000300011110	00847946031688	MAIN ASSY, PS Series, No Graphics, LCD, No Voice RCDG, 50HZ, Italian
20000801100011110	00847946032364	MAIN ASSY, PS Series, ECG On, LCD, Voice RCDG, Italian

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20000000000000110	00847946031244	MAIN ASSY, PA Series, No LCD, No Voice RCDG, Italian
20000001300011150	00847946032043	MAIN ASSY, PS Series, No Graphics, LCD, Voice RCDG, Chinese
20000000100011150	00847946031442	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Chinese
20000001100011150	00847946031824	MAIN ASSY, PS Series, LCD, Voice RCDG, Chinese, 50HZ
20000001100011250	00847946031893	MAIN ASSY, PS Series, LCD, Voice RCDG, Cantonese, 50HZ
20000000000000150	00847946031251	MAIN ASSY, PA Series, No LCD, No Voice RCDG, Chinese
20000001100011160	00847946031831	MAIN ASSY, PS Series, LCD, Voice RCDG, Dutch , 50HZ
20000001300011160	00847946032050	MAIN ASSY, AED Plus, PS Series, No Graphics, LCD, Voice RCDG, Dutch
20000001100011190	00847946031862	MAIN ASSY, PS Series, LCD, Voice RCDG, Greek
20000000000000210	00847946027230	MAIN ASSY, PA Series, No LCD, No Voice RCDG, Finnish
20000000300011220	00847946031718	MAIN ASSY, PS Series, No Graphics, LCD, No Voice RCDG, 50HZ, Sweden
20000000000000220	00847946031367	MAIN ASSY, PA Series, No LCD, No Voice RCDG, Swedish
20000000100011240	00847946031527	MAIN ASSY, PS Series, LCD, No Voice RCDG, 60HZ, Portuguese
20000001100011240	00847946031886	MAIN ASSY, PS Series, LCD, Voice RCDG, Portuguese, 60HZ
20000001100011330	00847946031923	MAIN ASSY, PS Series, LCD, Voice RCDG, Thai
20000000100011470	00847946031350	MAIN ASSY, PS Series, LCD, No Voice RCDG, 60HZ, Arabic
20000000300011340	00847946031749	MAIN ASSY, PS Series, No Graphics, LCD, No Voice RCDG, 50HZ, Arabic
20000001100011340	00847946031930	MAIN ASSY, PS Series, LCD, Voice RCDG, Arabic
20000000100011350	00847946031282	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Hebrew
20000000100011360	04560233596016	MAIN ASSY, PS Series, LCD, No Voice RCDG, Japanese
20000001100011360	04560233596030	MAIN ASSY, PS Series, LCD, Voice RCDG, Japanese
20001100100011360	04560233596405	MAIN ASSY, PS Series, LCD, WKLY No Voice RCDG, Japanese
20000000100011390	00847946031299	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, Dari/AFG
20000000100011420	00847946031312	MAIN ASSY, PS Series, LCD, No Voice RCDG, Switzerland/French
20000001100011420	00847946031954	MAIN ASSY, PS Series, LCD, Voice RCDG, AHA, Switzerland/French
20000000100011430	00847946031329	MAIN ASSY, PS Series, LCD, No Voice RCDG, Farsi
20000000100011460	00847946031343	MAIN ASSY, PS Series, LCD, No Voice RCDG, 50HZ, ICELAND
20000001100011520	00847946031961	MAIN ASSY, PS Series, LCD, Voice RCDG, Croatian, 50HZ
20000000100011540	00847946031589	MAIN ASSY, PS Series, LCD, No Voice RCDG, 60HZ, Taiwan
20000001100011540	00847946031985	MAIN ASSY, PS Series, LCD, Voice RCDG, Taiwan, 60HZ
20000000100011560	00847946031602	MAIN ASSY, PS Series, LCD, No Voice RCDG, Indonesian
20000001100011560	00847946032005	MAIN ASSY, PS Series W/Basic CVR, LCD, Voice RCDG, Indonesian
20000000300011230	00847946031725	MAIN ASSY, PS Series, No Graphics, LCD, No Voice RCDG, Spanish
20000000100011230	00847946099381	MAIN ASSY, PS Series, LCD, No Voice RCDG, 60HZ, Spanish
20000001100011230	00847946031879	MAIN ASSY, PS Series, LCD, Voice RCDG, Spanish, 60HZ
20000001300011230	00847946032067	MAIN ASSY, PS Series, No Graphics, LCD, Voice RCDG, Spanish
20000800100011230	00847946032296	MAIN ASSY, PS Series, ECG On, LCD, No Voice RCDG, 60HZ, Spanish
20000061100011540	00847946032128	MAIN ASSY, PS Series, LCD, Voice RCDG, Taiwan, Aviation
20000060100011130	00847946032098	MAIN ASSY, PS Series, LCD, No Voice RCDG, AUS, Aviation
20000700700011010	00847946002237	MAIN ASSY, PS Series, Fully Automatic, LCD, No Voice RCDG, DMST
20000700500011050	00847946032135	MAIN ASSY, PS Series, Fully Automatic, LCD, No Voice RCDG, 50HZ, UK
20000700500011080	00847946032142	MAIN ASSY, PS Series, Fully Automatic, LCD, No Voice RCDG, German
20000700500011160	00847946032166	MAIN ASSY, PS Series, Fully Automatic, LCD, No Voice RCDG, Dutch
20000703500011020	00847946032234	MAIN ASSY, PS Series, Fully Automatic, LCD, No Voice RCDG, French
20000700700011420	00847946032210	MAIN ASSY, PS Series, Fully Automatic, LCD, No Voice RCDG, Switzerland/French
20000700500011130	00847946023638	MAIN ASSY, Fully Automatic, PS Series, LCD, No Voice RCDG, 50HZ, AUS

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20000701500011050	00847946032227	MAIN ASSY, PS Series, Fully Automatic, LCD, Voice RCDG, English ERC
20000700700011090	00847946032180	MAIN ASSY, PS Series, Fully Automatic, LCD, No Voice RCDG, Switzerland/German
20000700500011100	00847946032159	MAIN ASSY, PS Series, Fully Automatic, LCD, No Voice RCDG, ERC, Spanish
20000700700011150	00847946048556	MAIN ASSY, PS Series, Fully Automatic, LCD, No Voice RCDG, Mandarin Chinese
20000700700011230	00847946024291	MAIN ASSY, PS Series, Fully Automatic, LCD, No Voice RCDG, DMST, AHA Spanish
20000700700011250	00847946032203	MAIN ASSY, PS Series, Fully Automatic, LCD, No Voice RCDG, Cantonese Chinese
20000700500011550	00847946032173	MAIN ASSY, Fully Automatic, PS Series, LCD, No Voice RCDG, 50HZ, Turkish
20000701500011550	00847946023362	MAIN ASSY, PS Series, Fully Automatic, LCD, Voice RCDG, Turkish

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