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Zentralstelle der Länder
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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 011882 0079 Rev. 00

Manufacturer:

PHYSIO-CONTROL, Inc.

11811 Willows Road N.E.
Redmond WA 98052
USA

Product Category(ies):

**ECG Monitors, Manual and Automatic External Defibrillators,
External Transcutaneous Pacemakers, with the Following
Optional Patient Parameter Monitoring Capability: Pulse
Oximetry, Invasive and Non-Invasive Blood Pressure,
Capnography (ETC02), Temperature, and Patient Data
Management System.**

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.:

72151769

Valid from:

2020-03-18

Valid until:

2024-05-26

Date,

2020-03-18

Christoph Dicks

Head of Certification/Notified Body

MDD Declaration of Conformity

DECLARATION OF CONFORMITY TO MEDICAL DEVICE DIRECTIVE 93/42/EEC, AS AMENDED THROUGH 2007/47/EC	
Legal Manufacturer Name	Physio-Control, Inc.
Legal Manufacturer Address	11811 Willows Road NE Redmond, WA 98052 USA
EU Authorized Representative Information (Name and Address)	Stryker European Operations Limited Anngrove, IDA Business & Technology Park Carrigtwohill, Co. Cork, T45 HX08 Ireland
Product Name	LIFEPAK® 1000 Defibrillator
See Appendix A for Device information, Appendix B for Accessories CE Marked with the Device, and Appendix C for Separately CE Marked Accessories.	
We declare that the CE-marked product listed above conforms to European Community Council Directive 93/42/EEC (Medical Device Directive), as amended through 2007/47/EC.	
We declare, under our sole responsibility, that products specified in Appendix A and B also conform to the following standards, regulations and directives.	
Directives/Regulations	Title/Description
2012/19/EU	Waste Electrical and Electronic Equipment Directive
2006/66/EC	Battery directive, as amended through 2013/56/EU
2011/65/EU	Restriction of the use of certain hazardous substances (RoHS Directive) as amended through 2015-856 • Annex I – Category 8 – Medical Devices • Annex III – Category 8 – Medical Devices • Annex IV – Exemption 17
Standards	Title/Description

EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices		
EN ISO 15223-1:2012	Symbols to be used with medical device labels, labeling and information to be supplied		
EN 60601-1:2006+A12:2014	Medical electrical equipment. Part 1: General requirements for safety		
EN 60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests		
EN 60601-1-6:2010 +A1:2015	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability		
EN 62281:2013	Safety of primary and secondary lithium cells and batteries during transport		
BS EN 62366:2008 -1:2015+A1:2015 2020 (IEC 62366:20072015+A1:20142020)	Medical devices – Part 1: Application of usability engineering to medical devices		
EN 60601-2-4:2011	Part 2-4: Particular requirements for the safety of cardiac defibrillators		
EN 60086-4:2015	Primary Batteries- Safety of Lithium Batteries		
EN 50419:2006 (Part of WEEE Directive)	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)		
EN 62304:2006+A1:2015	Medical Device Software – Software Life Cycle Processes		
EN 62133: 2013	Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications		
UL 2054:2004 R2011	UL Standard for Safety for Household and Commercial Batteries.		
Name and ID # of Notified Body (Enter N/A if Class I)	Description of Conformity Assessment Procedure	Device Risk Class	Issued Certificate Number (Enter N/A if Class I)
Notified Body 0123 TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 Munich, Germany	Annex II	IIb	G1 011882 0079 Rev. 00
Name of Head of Regulatory Affairs or Designee	Rebecca Funston		
Function of Head of Regulatory or Designee	Director, Global Regulatory and Clinical Affairs		

Place of Issue	Redmond, WA
Date of Issue (YYYY-MM-DD)	2021-08-25
Signature of Head of Regulatory Affairs or Designee	 Electronically signed by: Rebecca Furston Reason: I approve this document Date: Aug 25, 2021 16:32 GMT-7
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.	

Appendix A: Medical Devices

Catalog Number (REF#)	Part Number	Product Description	GMDN Code
99425-000138	320371500476	Arabic, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000139	320371500477	Arabic, ECG not allowed, Check Circulation voice prompt	48049
99425-000134	320371500478	Croatian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000143	320371500479	Croatian, ECG allowed, Check Pulse voice prompt, with ECG off	48049
99425-000135	320371500480	Croatian, ECG not allowed, Check Circulation voice prompt	48049
99425-000144	320371500481	Croatian, ECG not allowed, Check Pulse voice prompt	48049
99425-000126	320371500482	Czech, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000127	320371500483	Czech, ECG not allowed, Check Circulation voice prompt	48049
99425-000118	320371500484	Danish, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000119	320371500485	Danish, ECG not allowed, Check Circulation voice prompt	48049
99425-000109	320371500486	Dutch, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000102	320371500487	Dutch, ECG not allowed, Check Circulation voice prompt	48049
99425-000117	320371500488	English Intl, ECG allowed, Check Pulse voice prompt, with ECG off	48049
99425-000142	320371500489	English Intl, ECG not allowed, Check Pulse voice prompt	48049
99425-000113	320371500490	English Intl, ECG allowed, Check Circulation voice prompt, with ECG off	48049
99425-000096	320371500491	English Intl, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000111	320371500492	English Intl, ECG allowed, Check Pulse voice prompt, with ECG on	48049
99425-000094	320371500493	English Intl, ECG not allowed, Check	48049

Catalog Number (REF#)	Part Number	Product Description	GMDN Code
		Circulation voice prompt	
99425-000112	320371500494	English Intl, ECG not allowed, Check Pulse voice prompt, with 200/200/360 energy escalation	48049
99425-000152	320371500495	Finnish, ECG allowed, Check Pulse voice prompt, with ECG on	48049
99425-000128	320371500496	Finnish, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000150	320371500497	Finnish, ECG allowed, Check Pulse voice prompt, with ECG off	48049
99425-000151	320371500498	Finnish, ECG allowed, Check Pulse voice prompt, with ECG on, 200/200/360 energy escalation	48049
99425-000129	320371500499	Finnish, ECG not allowed, Check Circulation voice prompt	48049
99425-000168	320371500500	Finnish, ECG not allowed, Check Pulse voice prompt	48049
99425-000104	320371500501	French, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000097	320371500502	French, ECG not allowed, Check Circulation voice prompt	48049
99425-000162	320371500503	German, ECG allowed, Check Breathing voice prompt, with ECG on	48049
99425-000105	320371500504	German, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000098	320371500505	German, ECG not allowed, Check Circulation voice prompt	48049
99425-000147	320371500506	Greek, ECG allowed, Check Breathing voice prompt, with ECG on	48049
99425-000136	320371500507	Greek, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000154	320371500508	Greek, ECG allowed, Check Circulation voice prompt, with ECG on, 200/200/360 energy escalation	48049
99425-000137	320371500509	Greek, ECG not allowed, Check Circulation voice prompt	48049
99425-000140	320371500510	Hebrew, ECG allowed, Check Circulation	48049

Catalog Number (REF#)	Part Number	Product Description	GMDN Code
		voice prompt, with ECG on	
99425-000141	320371500511	Hebrew, ECG not allowed, Check Circulation voice prompt	48049
99425-000124	320371500512	Hungarian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000125	320371500513	Hungarian, ECG not allowed, Check Circulation voice prompt	48049
99425-000149	320371500514	I Port, ECG allowed, Check Breathing voice prompt, with ECG on	48049
99425-000120	320371500515	I Port, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000121	320371500516	I Port, ECG not allowed, Check Circulation voice prompt	48049
99425-000148	320371500517	I Port, ECG not allowed, Check Pulse voice prompt	48049
99425-000107	320371500518	Italian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000100	320371500519	Italian, ECG not allowed, Check Circulation voice prompt	48049
99425-000164	320371500520	Japanese, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000163	320371500521	Japanese, ECG not allowed, Check Circulation voice prompt	48049
99425-000169	320371500522	Lithuanian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000170	320371500523	Lithuanian, ECG not allowed, Check Circulation voice prompt	48049
99425-000122	320371500524	Norwegian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000123	320371500525	Norwegian, ECG not allowed, Check Circulation voice prompt	48049
99425-000110	320371500526	Polish, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000103	320371500527	Polish, ECG not allowed, Check Circulation voice prompt	48049
99425-000157	320371500528	Russian, ECG allowed, Check Circulation voice prompt, with ECG on	48049

Catalog Number (REF#)	Part Number	Product Description	GMDN Code
99425-000194	320371500529	Russian, ECG allowed, Check Circulation voice prompt, with ECG off	48049
99425-000132	320371500530	Russian, ECG allowed, Check Breathing voice prompt, with ECG on	48049
99425-000133	320371500531	Russian, ECG not allowed, Check Circulation voice prompt	48049
99425-000130	320371500532	Serbian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000145	320371500533	Serbian, ECG allowed, Check Pulse voice prompt, with ECG off	48049
99425-000131	320371500534	Serbian, ECG not allowed, Check Circulation voice prompt	48049
99425-000146	320371500535	Serbian, ECG not allowed, Check Pulse voice prompt	48049
99425-000158	320371500536	Slovak, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000159	320371500537	Slovak, ECG not allowed, Check Circulation voice prompt	48049
99425-000155	320371500538	Slovenian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000160	320371500539	Slovenian, ECG allowed, Check Pulse voice prompt, with ECG off	48049
99425-000156	320371500540	Slovenian, ECG not allowed, Check Circulation voice prompt	48049
99425-000161	320371500541	Slovenian, ECG not allowed, Check Pulse voice prompt	48049
99425-000106	320371500542	Spanish, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000099	320371500543	Spanish, ECG not allowed, Check Circulation voice prompt	48049
99425-000153	320371500544	Spanish, ECG not allowed, Check Pulse voice prompt	48049
99425-000108	320371500545	Swedish, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000116	320371500546	Swedish, ECG allowed, Check Pulse voice prompt, with ECG on	48049
99425-000114	320371500547	Swedish, ECG allowed, Check Pulse	48049

Catalog Number (REF#)	Part Number	Product Description	GMDN Code
		voice prompt, with ECG on, 200/200/360 energy escalation	
99425-000101	320371500548	Swedish, ECG not allowed, Check Circulation voice prompt	48049
99425-000115	320371500549	Swedish, ECG not allowed, Check Pulse voice prompt	48049
99425-000171	320371500550	Romanian, ECG allowed, Check Breathing with ECG on	48049
99425-000172	320371500551	Romanian, ECG not allowed, Check Breathing	48049
99425-000177	320371500552	Persian, ECG allowed, Check Pulse with ECG on	48049
99425-000178	320371500553	Persian, ECG not allowed, Check Pulse	48049
99425-000179	320371500554	Turkish, ECG allowed, Check Circulation with ECG on	48049
99425-000180	320371500555	Turkish, ECG not allowed, Check Circulation	48049
99425-000173	320371500556	Cantonese, ECG allowed, Check Pulse with ECG on	48049
99425-000175	320371500557	Cantonese, ECG not allowed, Check Pulse	48049
99425-000174	320371500558	Mandarin ECG allowed, Check Pulse with ECG on	48049
99425-000176	320371500559	Mandarin, ECG not allowed, Check Pulse	48049
99425-000182	320371500560	Taiwan Mandarin, ECG allowed, Check Pulse with ECG on	48049
99425-000183	320371500561	Taiwan Mandarin, ECG not allowed, Check Pulse	48049
99425-000184	320371500562	Korean, ECG allowed, Check Pulse with ECG on	48049
99425-000185	320371500563	Korean, ECG not allowed, Check Pulse	48049
99425-000233	320371500583	Intl English, ECG not allowed, Check Circulation, custom settings for New Zealand	48049
99425-000240	320371500584	Intl English, ECG not allowed, Check Circulation, custom settings for New Zealand	48049

Catalog Number (REF#)	Part Number	Product Description	GMDN Code
99425-000241	320371500585	Intl English, ECG allowed, Check Circulation, custom settings for New Zealand	48049

Catalog Number (REF#)	Part Number	Product Description	GMDN Code
99425-000025	331706400001	English, ECG allowed, Check Pulse voice prompt, with ECG on	48049
99425-000023	331706400002	English, ECG not allowed, Check Pulse voice prompt	48049
99425-000207	331706400003	English Intl, ECG allowed, Check Pulse voice prompt, with ECG off	48049
99425-000208	331706400004	English Intl, ECG not allowed, Check Pulse voice prompt	48049
99425-000209	331706400005	English Intl, ECG allowed, Check Circulation voice prompt, with ECG off	48049
99425-000210	331706400006	English Intl, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000211	331706400007	English Intl, ECG allowed, Check Pulse voice prompt, with ECG on	48049
99425-000212	331706400008	English Intl, ECG not allowed, Check Circulation voice prompt	48049
99425-000213	331706400009	English Intl, ECG not allowed, Check Pulse voice prompt, with 200/200/360 energy escalation	48049
99425-000214	331706400010	French, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000215	331706400011	French, ECG not allowed, Check Circulation voice prompt	48049
99425-000216	331706400012	Russian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000217	331706400013	Russian, ECG allowed, Check Circulation voice prompt, with ECG off	48049
99425-000218	331706400014	Russian, ECG allowed, Check Breathing voice prompt, with ECG on	48049
99425-000219	331706400015	Russian, ECG not allowed, Check	48049

Catalog Number (REF#)	Part Number	Product Description	GMDN Code
		Circulation voice prompt	
99425-000220	331706400016	Spanish, ECG allowed, Check Circulation voice prompt, with ECG on	48049
99425-000221	331706400017	Spanish, ECG not allowed, Check Circulation voice prompt	48049
99425-000222	331706400018	Cantonese, ECG allowed, Check Pulse with ECG on	48049
99425-000223	331706400019	Cantonese, ECG not allowed, Check Pulse	48049
99425-000189	331706400020	Brazilian, ECG allowed, Check Circulation with ECG on	48049
99425-000190	331706400021	Brazilian, ECG not allowed, Check Circulation	48049
99425-000192	331706400030	Thai, ECG allowed, Check Pulse with ECG on	48049
99425-000187	331706400031	Thai, ECG not allowed, Check Pulse	48049

Appendix B: Accessories CE Marked with the Device

Catalog Number (REF#)	Part Number	Product Description	GMDN Code
11141-000100	3206245-005	Assembly Battery Replacement Kit * (Includes: DISCHARGER ASSY- PRIMARY BATTERY, LP 1000 (3205366- xxx))	38558
11141-000156	3205379-007	ASSY-BATTERY,PRIMARY,5/4C CELL,LIMN02,LP1000 *	38558
11141-000160	3310523-004	BATTERY PACK - LITHIUM ION, LP 1000 *	36534

* This is a user-replaceable component of the main medical device, not an accessory.

Appendix C: Separately CE Marked Accessories

Medical device accessories:

QUIK-COMBO™ pacing/defibrillation/ECG electrodes with REDI-PAK™
 Infant/Child reduced energy electrodes
 3-Wire ECG Cables
 Cleartrace® ECG Electrodes
 Kendall® ECG Electrodes

Non-medical accessories:

IrDA Adapter (attachment for a PC)
 Battery Charger

LP 1000 DoC

Final Audit Report

2021-08-25

Created:	2021-08-24
By:	Alyssa Burke (alyssa.burke@stryker.com)
Status:	Signed
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"LP 1000 DoC" History

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