Declaration of Conformity

DECLARATION OF CONFORMITY TO MEDICAL DEVICE REGULATION 2017/745	
Legal Manufacturer Name	Physio-Control, Inc.
Legal Manufacturer SRN	US-MF-000000290
Legal Manufacturer Address	11811 Willows Road NE Redmond, WA 98052 USA
EU Authorized Representative Information (Name and Address and SRN if applicable)	Stryker European Operations Limited Anngrove, IDA Business & Technology Park Carrigtwohill, Co. Cork, T45 HX08 Ireland SRN**:** IE-AR-000000092
See Appendix A for information on the Replacement Kit for CHARGE-PAK™ Charger and QUIK-PAK™ Electrodes, which includes the QUIK-PAK™ Pacing/ECG/Defibrillation Electrodes	
We hereby declare under our sole responsibility that these products conform with the relevant provisions of the Medical Device Regulation 2017/745. Each of the listed and CE Marked products in the appendix A has been verified against defined criteria and found to be in compliance with the General Safety and Performance Requirements of Annex I in the Medical Device Regulation 2017/745 prior to being placed on the market. This Declaration of Conformity is valid in conjunction with the respective production release records for the referenced devices. This declaration applies to CE Marked products produced after the date issuance of this declaration and before it is superseded by another declaration or withdrawn.	
We declare, under our sole responsibility, that the products specified in the product list (Appendix A) also conform to the regulations, standards, and directives in Appendix B.	

Name and ID # of Notified Body* *If Class I (Self-Certified) enter 'Not applicable' in the corresponding areas.	**Description of Conformity Assessment Procedure**	**Issued Certificate Number***
Not applicable	Conformity to Annex II and Annex III of the Regulation (EU) 2017/745	Not applicable
Reference to Common Specifications	Not applicable	
Additional Information	Not applicable	
Name of Person Responsible for Regulatory Compliance or Designee	Kathryn Janecke	
Function of Person Responsible for Regulatory Compliance or Designee	Senior Director – Regulatory, Quality and Clinical Affairs	
Place of Issue	11811 Willows Road NE Redmond, WA 98052 USA	
Date of Issue/Effective Date (YYYY-MM-DD)	26-May-2022	
Signature of Person Responsible for Regulatory Compliance** **Translations of this Declaration of Conformity are a true and accurate representation of the original signed English Declaration of Conformity.	 *Electronically signed by:* *Kathryn Janecke* *Reason: I approve this document* *Date: May 26, 2022 20:54 CDT*	

Appendix A:

Product Description Name	Catalog Number	Basic UDI-DI	Risk Class	EMDN/CND Code	Intended Purpose
SHIPPING ASSY-C-P, Q-P,REPL KIT, 2 ELECTRODE,	11403-000001	08858250000246RM	I	Z12030580	The QUIK-PAK electrodes, which are included as part of the Replacement Kit for CHARGE-PAK Charger and QUIK-PAK Electrodes, are an accessory of the LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators. The LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators are indicated for use on patients in cardiac arrest. The patient must be unresponsive (unconscious), not breathing normally, and showing no signs of circulation (for example, no pulse, no coughing, or no movement). The LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators are intended for use by personnel who have been trained in their operation. Users should have received training in basic life support/AED, advanced life support or a physician-authorized emergency medical response training program. The defibrillators may be used with the QUIK-PAK™ defibrillation pads only on adults and children who are 8
SHIPPING ASSY-C-P, Q-P,REPL KIT, 1 ELECTRODE	11403-000002				

Product Description Name	Catalog Number	Basic UDI-DI	Risk Class	EMDN/CND Code	Intended Purpose
					years old or more, or who weigh more than 25 kg (55 lbs). The defibrillators may be used on children who are less than 8 years old or weigh less than 25 kg (55 lbs) with Infant/Child Reduced Energy Defibrillation Electrodes. The defibrillators may be used with the CHARGE-PAK™ battery charger. When applied to the victim, the QUIK-PAK electrodes (pads) work with the defibrillator to monitor the heart rhythm and identify when a shock should be delivered. If victim care is transferred to emergency medical personnel, these electrode pads can be disconnected from the defibrillator and reconnected to other AEDs or defibrillators that are compatible with QUIK-COMBO® electrodes.

Appendix B:

Standards/Regulations/Directives	Title/Description
EN ISO 10993-1:2020	Biological evaluation of Medical Devices Part 1: Evaluation and testing
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2012	Application of risk management to medical devices
EN 60601-1_2006+A12:2014	General requirements for safety for medical electrical equipment
EN 60601-1-6:2010+A1:2015	Safety requirements for usability
EN 60601-1-11:2015	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 62366:2008 +A1:2015	Application of usability engineering to medical devices
EN 60601-2-4:2011	Safety requirements for cardiac defibrillators
EN 60086-4:2015	Safety of lithium batteries
EN 62281:2013	Safety of primary and secondary lithium cells and batteries during transport
Regulation (EU) 2017/745	Medical Device Regulation (MDR)
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) • Annex I – Category 8 – Medical Devices • Annex IV – Exemption 17

3344205_A_QUIK-PAK Electrode and Replacement Kit for CHARGE-PAK Charger and QUIK-PAK Electrodes MDR DoC

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