stryker

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 **Edge System 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 This declaration applies to CE Marked products produced after the date issuance of this declaration and before it is superseded by another declaration or withdrawn.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	Rebecca Funston	
Function of Person Responsible for Regulatory Compliance or Designee	Director, Global Regulatory & Clinical Affairs	
Place of Issue	11811 Willows Road NE Redmond, WA 98052 USA	
Date of Issue/Effective Date (YYYY-MM-DD)	2021-03-24	
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:* *Rebecca Funston* *Reason: I approve this document* *Date: Mar 24, 2021 13:50 GMT*	

Appendix A:

Product/Trade Name and Variants	Catalog Number	Basic UDI-DI	Risk Class	☐ CND Code ☒ GMDN Code	Intended Purpose
QUIK-COMBO RTS Adult Pacing/Defibrillation/ECG Electrodes Radiotransparent System	11996-000090	08858250000244RH	I	44771	The intended purposes of the Edge System Electrodes are as multifunction electrodes providing a means to transfer energy from the defibrillator to the adult or pediatric patient for therapeutic defibrillation or as a means for transferring a waveform for shock analysis.
QUIK-COMBO Adult Pacing/Defibrillation/ECG Electrodes	11996-000091	08858250000244RH	I		
QUIK-COMBO Adult Pacing/Defibrillation/ECG Electrode with REDI-PAK Preconnect System	11996-000017	08858250000244RH	I		
QUIK-COMBO RTS Pediatric Pacing/Defibrillation/ECG Electrodes Radiotransparent System	11996-000093	08858250000245RK	I	41857	

Appendix B:

Standards/Regulations/Directives	Title/Description
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
BS EN ISO 13485:2016	Quality Management Systems - Requirements for regulatory purposes
EN 60601-1:2006+A12:2014	Medical electrical equipment. Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. Collateral standard: Electromagnetic disturbances. 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 62366:2008+ A1:2015	Medical devices. Application of usability engineering to medical devices
EN 60601-2-4:2011	Medical electrical equipment – Part 2-4: Particular requirements for the safety of cardiac defibrillators
EN ISO 10993-1:2009+AC:2010	Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process
Regulation (EC) No 1907/2006	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
Directive 2011/65/EU	Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive)
Directive 2012/19/EU	Waste Electrical and Electronic Equipment (WEEE)