This Declaration of Conformity is issued under the sole responsibility of the manufacturer. The devices covered by the present Declaration is in conformity with all regulations or directives below, including compliance with related General Safety and Performance Requirements.

1. Object of the declaration:

<table>
<tr><td>Product Name</td><td>ALS and BLS Pads</td></tr>
<tr><td>Product Type</td><td>Multifunction Defibrillator Electrode Pads</td></tr>
<tr><td>Intended Purpose</td><td>The ALS and BLS Pads do not have an intended use as a stand-alone product. The ALS and BLS Pads are intended for use in conjunction with compatible AED’s and Defibrillator/Monitor systems to provide an electrical connection between the defibrillator and the patient for the purpose of defibrillation, ECG monitoring, cardioversion and pacing.</td></tr>
<tr><td>Product Part Number(s) and Descriptions</td><td>
<table>
<tr><th>Catalog Number</th><th>Product Description</th></tr>
<tr><td>989803139261</td><td>HeartStart SMART Pads II</td></tr>
<tr><td>989803149981</td><td>HeartStart SMART Pads III (1 set)</td></tr>
<tr><td>989803149991</td><td>HeartStart SMART Pads III (5 sets)</td></tr>
<tr><td>989803158211</td><td>HeartStart Defibrillator Pads, DP2/DP6 (1 set)</td></tr>
<tr><td>989803158221</td><td>HeartStart Defibrillator Pads, DP2/DP6 (5 sets)</td></tr>
</table>
</td></tr>
<tr><td>Product Options/Accessories</td><td>N/A. The ALS and BLS Pads do not contain accessories within the scope of the EU MDR Regulations.</td></tr>
<tr><td>Basic UDI-DI</td><td>ALS and BLS Pads: 0884838BM480T6</td></tr>
<tr><td>Control Indicator</td><td>
<table>
<tr><th>Part Number:</th><th>Lot Number</th></tr>
<tr><td>989803139261</td><td>210426-0958</td></tr>
<tr><td>989803149981</td><td>210505-4031</td></tr>
<tr><td>989803149991</td><td>210506-4032</td></tr>
<tr><td>989803158211</td><td>210503-1801</td></tr>
<tr><td>989803158221</td><td>210510-1802</td></tr>
</table>
</td></tr>
<tr><td>CND Code and Description</td><td>ALS Pads: Z12030585 – Defibrillators - Consumables
BLS Pads: Z12030585 – Defibrillators - Consumables</td></tr>
</table>

The object of the Declaration described above is in conformity with the following regulations and directives:

EU Regulation	**Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 on medical devices (EU MDR)**
Device Risk Classification	Class I based on Annex VIII and Rule 1
Conformity Assessment Path	Not applicable for Class I medical devices
Notified Body Name, Address, and ID	Not applicable for Class I medical devices
Certificate(s) issued	Not applicable for Class I medical devices
Standards	The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below. Refer to Attachment A
Common Specifications	Not applicable. There are no common specifications relevant to this device type issued by MDCG.
EU Directive	**Directive 2011/65/EU of the European Parliament and of the Council of 08 June 2011 on the restrictions of the use of certain hazardous substances in electrical and electronic equipment, amended up to and inclusive of Directive (EU) 2017/2102 (RoHS)**
	Refer to LC2385 ALS and BLS Pads Technical Document section 4.3
EU Directive	**Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC**
	Refer to LC2385 ALS and BLS Pads Technical Document section 4.3

2. Additional information:

Manufacturer	Philips Medical Systems 22100 Bothell Everett Highway Bothell, WA 98021-8431 USA SRN: US-MF-000002128
EU Authorized Representative	Philips Medical Systems Nederland B.V. Veenpluis 6 5684PC Best The Netherlands SRN: NL-AR-000001422
Quality Certificates Issued	The Manufacturer is certified by TÜV SÜD to the following: EN ISO 13485:2016 Quality Management: Q5 078838 0012 MDSAP Certificate by TÜV SÜD: QS6 078838 0013

Signature (signed for and on behalf of Philips Medical Systems): Date of Issue: 07 May 2021

Printed Name: Michael F. Petrini
Title: Head, Regulatory Affairs – Emergency Care

Place of Issue: Bothell, WA
Document#: LC2385-201
Date of Expiration: 26-MAY-2024

3. Attachment A

Applied Standards and Guidance for the BLS Pads	
Standard number	**Standard Description**
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2007	Risk Management for Medical Devices as modified by EN ISO 14971: 2012
EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices
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 ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	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
MEDDEV 2.7/1 Rev 4	Guidelines on Medical Devices Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC
IEC 60601-1:2005+A1:2012	Medical Electrical Equipment - Part l: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2:2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6:2010+A1:2013	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