

CÔNG TY TNHH ASIA ACTUAL VIETNAM
MST: 0316765196

TÀI LIỆU ĐƯỢC KÝ BẰNG CHỮ KÝ SỐ

Người đại diện hợp pháp của cơ sở
Giám đốc
Võ Trung Việt
(đã ký)

Apple, Inc.
DECLARATION OF CONFORMITY CERTIFICATE

LEGAL MANUFACTURER:	INITIAL ISSUE DATE: 20 October 2020	REVISION: A
	RE-ISSUE DATE: N/A	REVISION: N/A

Apple Inc.
 One Apple Park Way
 Cupertino, CA 95014 USA
<http://www.apple.com>

MANUFACTURING SITE: *(if different)*
Same as Legal Manufacturer

EUROPEAN UNION AUTHORIZED REPRESENTATIVE:
 Apple Distribution International
 Hollyhill Industrial Estate
 Hollyhill, Cork, Ireland
medicalcompliance@group.apple.com

NOTIFIED BODY:
 TÜV SÜD Product Service GmbH Zertifizierstellen
 Ridlerstraße 65
 80339 MÜNCHEN
 Germany
 +49 (89) 50084261
<http://www.tuev-sued.de/ps>

PRODUCT: ECG app

SOFTWARE VERSION: 2.X

PRODUCT UNIQUE IDENTIFICATION ECG Watch App 00190199649286
 ECG iPhone App 00190199649293

PRODUCT CATEGORY: Software Used in Heart Rhythm Analysis

CLASSIFICATION: Class IIa per the Council Directive 93/42/EEC of 14 June 1993 Annex IX, rule 10.

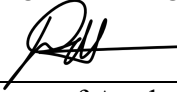
We hereby declare that the products identified above are in conformity with all relevant provisions of Council Directive 93/42/EEC of 14 June 1993 Concerning Medical Devices, as amended by 2007/47/EC. This Declaration of Conformity is made under Annex II.3 of this directive and is in conformity with the following standard(s) and other normative document(s).

- EN ISO 13485:2016
- EN ISO 14971:2012
- EN 62366-1:2015
- EN 62304:2006+AMD1:2015
- EN 82304-1:2017
- EN ISO 15223-1:2016

This Declaration of Conformity applies to all products contained on this certificate distributed on or after 20 October 2020. All supporting information is retained under the control of the legal manufacturer.

The legal manufacturer is exclusively responsible for the Declaration of Conformity.

SIGNATURE/DATE OF ISSUE:



Signature of Apple Inc Representative

David Amor

Print Name

Head of Regulatory Affairs and Quality Assurance
Title

Cupertino, CA USA

Apple Inc. Issuing Location

20 October 2020

Date of Initial Issue/Re-issue

14 February 2024

Expiration Date

EC Certificate No. G1 082774 0024 Rev. 00

Category: Software Used in Heart Rhythm Analysis