



DEVICE DETAILS

NAME OF DEVICE	Apple ECG APP
ESTABLISHMENT NAME	NYPRAX BUSINESS SOLUTIONS
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB7992021-54025
BRAND NAME	APPLE
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>The ECG app comprises a pair of mobile medical apps—one on Apple Watch and the other on the iPhone—intended to create, record, store, transfer, and display a single channel electrocardiogram (ECG) similar to a Lead I ECG. The ECG Apple Watch App is intended to analyze electrocardiograph data and determine the presence of AFib, sinus rhythm or high heart rate (no detected AF with heart rate 100-150 bpm) on a classifiable waveform. The ECG iPhone App is included in the Health App, which allows users to store, manage, and share health and fitness data, and comes pre-installed on every iPhone.</p>
DEVICE INTENDED PURPOSE	<p>The ECG app is a software-only mobile medical application intended for use with the Apple Watch to create, record, store, transfer, and display a single channel electrocardiogram (ECG) similar to a Lead I ECG. The ECG app determines the presence of atrial fibrillation (AFib), sinus rhythm and high heart rate (no detected AF with heart rate 100-150 bpm) on a classifiable waveform. The ECG 2.0 app is not recommended for users with other known arrhythmias. The ECG app is intended for over-the-counter (OTC) use. The ECG data displayed by the ECG app is intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating AFib from normal sinus rhythm and not intended to replace traditional methods of diagnosis or treatment.</p>
VALIDITY DATE OF REGISTRATION	01/02/2021 - 31/01/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	ECG Watch App	00190199649286
2	ECG iPhone App	00190199649293