



DEVICE DETAILS

NAME OF DEVICE	APPLE SLEEP APNEA NOTIFICATION FEATURE
ESTABLISHMENT NAME	NYPRAX BUSINESS SOLUTIONS
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB6685125-193304
BRAND NAME	APPLE
MEDICAL DEVICE CATEGORY	MD 1111 - Software
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>The Sleep Apnea Notification Feature (SANF) is an over-the-counter mobile medical application (MMA) that is intended to identify patterns of breathing interruptions suggestive of moderate-severe sleep apnea and provide a notification to the user. The number of breathing interruptions per sleep session is represented as the Breathing Disturbances (BD). The SANF analyzes accelerometer data from the Apple Watch to calculate BD values during a user's sleep session and analyzes the BD results in discrete consecutive 30-day windows. The SANF analyzes these results and surfaces a notification to the user when there is sufficient information within the specific evaluation window suggestive of moderate-to-severe sleep apnea. The SANF also provides visualizations depicting the user's BD data. The nightly BD data is stored in HealthKit and displayed in Apple's Health app.</p>
DEVICE INTENDED PURPOSE	<p>The Sleep Apnea Notification Feature (SANF) is a software-only mobile medical application that analyzes Apple Watch sensor data to identify patterns of breathing disturbances suggestive of moderate-to-severe sleep apnea and provides a notification to the user. This feature is intended for over-the-counter (OTC) use by adults age 18 and over who have not previously received a sleep apnea diagnosis and is not intended to diagnose, treat, or aid in the management of sleep apnea. The absence of a notification is not intended to indicate the absence of sleep apnea.</p>
VALIDITY DATE OF REGISTRATION	02/01/2025 - 01/01/2030

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Sleep Apnea Notification Feature	00195949116193
2	Sleep Apnea Notification Feature	00195949116209