DATA SHEET

ECG247 Heart Monitoring Device

RECORDER SYSTEM AND BELONGING SOFTWARE

ECG247 Smart Sensor - Electrocardiographic long-term ambulatory recorder/analyser GMDN 44423 ECG247 Electrode - Ambulatory recorder conductive patch GMDN 62597 ECG247 APP software - Single-patient physiologic monitoring system application software GMDN 59378 ECG247 Web software - Electrocardiographic long-term ambulatory recording analyser application software GMDN 41651



CERTIFICATION

CE: 10000366191-PA-NA-NOR, (MDD 93/42/EEC), Class IIa Medical Device Other: Bluetooth SIG., BLE

Biocompatibility: According to ISO 10993.

DIMENSIONS

L x w x d: Ø4,01 x 1,09 cm (d), (Sensor), 13,3 x 5,0 x 0,59 cm (Electrode) **Weight:** 7,2 gr (Sensor), 6,5 gr (Electrode) Patch area skin contact: 35,996 cm2 (Electrode)

BATTERY POWER

Maxell CR 2032 3V single use Lithium 230 mAh **L x w:** 3.2 x 20 mm

RADIO BLE

Transmission power <1 mW/0dBm Bluetooth operating range up to 10 m

ECG RECODER

Sampling rate: 256 Hz Bandwidth: 0,5 Hz to 40 Hz Recording resolution: 16-bit Binary code, sensitivity: 0,143 μV **Dynamic range:** ± 10 mV **Amplifier input impedance:** $> 10 \text{ M}\Omega$

WATER PROTECTION

IP 44 (protected against showering)

STORAGE

Temperature: -25 – +70 °C **Humidity:** 0 – 90% **Pressure:** 500 –1060 hPa

RECOMMENDED USERS

Not intended for: Pregnant, children < 18 years, BMI >40 Not to be used by persons with pacemakers Not to be used during defibrillation

SOFTWARE

ECG247APP (requires Android version 9.0 or newer, iOS 11 or newer) ECG247Web portal (requires web-browser for PC/MAC: Chrome, Edge, Safari) Secured Back-end-services (hosted by ECG247)

DATA SECURITY AND PRIVACY

2-factor user authentication Data security according to requirements for sensitive medical information Privacy according to GDPR

ARRHYTHMIA ANALYSER

(2-stage analyser including Deep Learning Method) Atrial Fibrillation Atrial Flutter Pause Ventricular Tachycardia Supraventricular Tachycardia Bradycardia (HR < 30 b/min) Tachycardia (HR>180 b/min) Ventricular Extrasystole Supraventricular Extrasystole

RE-USABLE SENSOR

After cleaning and disinfecting with a damp cloth/wipe (Ecolab Incidin Duo or similar)

TEST DURATION

Recommended test duration: minimum 3 days Maximum test duration: 14 days

ACCESSORIES

Smartphone with mobile data communication

