

## ECG247 Heart Monitoring Device

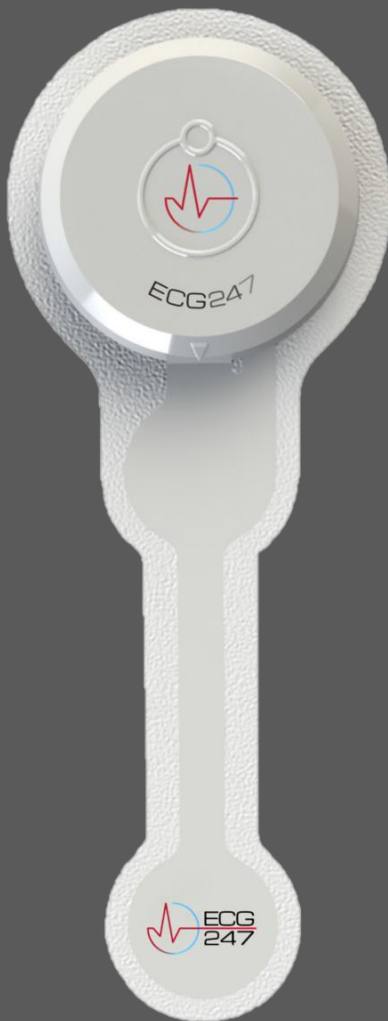
### ELECTROCARDIOGRAPHIC LONG-TERM AMBULATORY RECORDER SYSTEM AND BELONGING SOFTWARE

ECG247 Smart Sensor - Electrocardiographic long-term ambulatory recorder/analyser **GMDN 38729**

ECG247 Electrode - Ambulatory recorder conductive patch **GMDN 62597**

ECG247 APP software - Single-patient physiologic monitoring system application software **GMDN 62169**

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 cm<sup>2</sup>  
(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 RECORDER

**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 MΩ  
**Leads:** Dual lead (lead A and B)

#### WATER PROTECTION

IP 44 (protected against showering)

#### STORAGE

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

#### NOT INTENDED FOR:

Pregnant, children < 10 kg,  
BMI >40, persons with  
pacemakers and 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 14 days

#### ACCESSORIES

Smartphone with mobile  
data communication