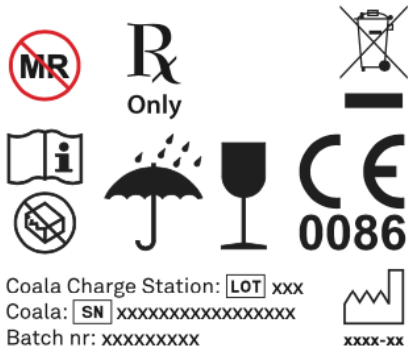


# Regulatory and certifications



Coala-Life AB  
 info@coalalife.com  
 www.coalalife.com  
 Riddargatan 18  
 114 51 Stockholm  
 Sweden

Coala Heart Monitor US Rx  
 Art nr: REF 201  
 Bluetooth MAC Address:  
 XX:XX:XX:XX:XX:XX  
 FCCID: 2AL07CHM



Coala Charge Station: LOT xxx  
 Coala: SN xxxxxxxxxxxxxxxxx  
 Batch nr: xxxxxxxxx



## 510(k) clearances

Telephone electrocardiograph transmitter and receiver	21 CFR 870.2920	Class II	DXH
Electrocardiograph (ECG)	21 CFR 870.2340	Class II	DPS
Stethoscope	21 CFR 870.1875	Class II	DQD
Phonocardiograph	21 CFR 870.2390	Class I	DQC



Verified against the IEC standards:

- **IEC60601-2-47** Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
- **IEC60601-2-27** Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
- **IEC60601-2-25** Particular requirements for the basic safety and essential performance of electrocardiographs
- **ANSI/AAMI EC57** Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms (automatic Interpretation)

