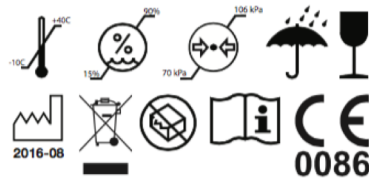


Regulatory and validation support



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The Coala Heart Monitor, the Coala Heart Monitor Pro and related software and apps hold a Class IIa Medical Device Approval by BSI. Coala-Life AB is certified according to the ISO 13485:2016 standard



The Coala Heart Monitor has a FDA 510(k) approval for Rx indications in the following product classes:

Telephone electrocardiograph transmitter and receiver	21 CFR 870.2920	Class II	DXH
Electrocardiograph	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
- IEC60601-2-27
- IEC60601-2-25
- ANSI/AAMI EC57