

# Technical and regulatory information

HARDWARE - C3W	
Medical purpose / type of ECG recorder	Holter, ambulatory ECG (reusable device)
Wear time / recording period	Up to 14 days on a single charge
Recording format	Continuous
Dimensions & weight	85 x 80 x 15 mm; 36 g
IP rating	IP67 (dustproof / waterproof down to 1 meter for 30 minutes)
Number of ECG channels	3
Sampling rate	256 Hz
Resolution	24-bit
Input impedance	10 Mohm
Battery / power requirement	Rechargeable lithium-polymer battery, 3.7 V, 680 mAh
Performance standard	IEC 60601-2-47 – Design verification for ambulatory ECG
Charger	Charging adapter included (USB-C and USB-A connections)
Charging time	Approx. 2 hours
Accelerometer	Integrated 3-axis
Electrode requirements	Three standard single-use snap electrodes
Placement on body	Torso, midsternal line
SOFTWARE - APEX	
Supported computer platforms	Windows and macOS
Export file format	EDF (European Data Format)
Wireless connectivity	Compatible with iOS and Android devices
Integration options	Entra ID; AD; Platform API (by request); SDK for iOS & Android
DEVICE AND COMPANY APPROVALS	
CE-mark	EU MDR 2017/745, Class IIa medical device
Quality management system	ISO 13485
Safety standards	IEC 60601-1; IEC 60601-1-11; IEC 60601-2-47; ISO 14971:2019
Data protection compliance	General Data Protection Regulation (GDPR)
Notified body	TÜV SÜD Product Service GmbH (CE 0123)

