	REC-73-8 EU Declaration of Conformity	
	REC-73-8 EU Declaration of Conformity SmartWatch 287-2 20221109.docx	
	Based on: TEMPLATE REC-73-8 EU Declaration of Conformity v1.1	Author: Willem Baelde Date: 30-Aug-23

EU Declaration of Conformity

Name of the Device: CardioWatch 287-2 Bracelet
 Basic UDI-DI: 8720256776CW287-2CA
 EMDN classification: Z12040113 - Regional Plethysmographs
 Risk class: IIa
 Classification based on: Rules 10 & 11

Intended purpose:

The CardioWatch 287-2 is a wireless remote monitoring intended for continuous collection of physiological data in home and healthcare settings. This includes heart rate, heart rate variability (R-R interval), respiration rate, activity, sleep, ECG, SpO2, Body Temperature and Blood Pressure. Data is transmitted wirelessly from the device via the application or gateway to a server or health cloud where it is stored and made available for further analysis.

Place of issue: Den Haag, The Netherlands
 Date of issue: November 9, 2022

Manufacturer: Corsano Health B.V.
 Manufacturer address: Wilhelmina van Pruisenweg 35
 2595 AN Den Haag, The Netherlands
 Single Registration Number (SRN): NL-MF-000013825

Notified Body: KIWA DARE B.V.
 Notified Body Address: Vijzelmolenlaan 7
 3447 GX Woerden, The Netherlands
 NB Identification number: 1912
 Certificate number: 20M00011CRT01


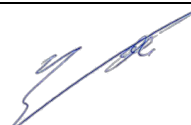
Device is in conformity with:


- Regulation (EU) 2017/745 on Medical Devices (EU-MDR)
- Directive 2011/65/EU on the Restriction of Hazardous Substances (RoHS)
- Regulation (EU) 2016/679 on General Data Protection Regulation (GDPR)
- Regulation (EU) 2014/53 on Radio Equipment (RED)

EU-MDR 2017/745 Conformity assessment route:

- Quality Management System and Technical Documentation (Annex IX)

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Name	Role	Signature
Peter Stas	Chief Executive Officer	
Willem Baelde	Chief Quality & Regulatory Affairs	

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Common Specifications, Used Standards & other supporting documents:

- EN-IEC 60601-1:2006 + AC:2010 + A1:2013 + A12:2014
- EN 60601-1-2:2015
- EN-IEC 60601-1-6:2010 + A1:2015
- IEC 60601-1-8:2006 + IEC 60601-1-8:2006/A1:2012 + IEC 60601-1-8:2006/A2:2020
- EN-IEC 60601-1-11:2015
- EN- ISO 60601-2-47:2012
- EN- ISO 80601-2-55:2018
- EN- ISO 80601-2-56:2017
- EN- ISO 80601-2-61:2017
- ETSI EN 300 328 V2.1.1:2016
- ETSI EN 300 328 V2.2.2:2019
- EN 55011:2009 + A1:2010
- EN-IEC 82304-1:2016
- EN-IEC 62304:2006 + AC:2008 + A1:2015
- EN-IEC 62366-1:2015 + A1:2020
- EN ISO 13485:2016
- EN-ISO 14971:2019
- EN-ISO 14155:2020
- ISO 10993-1:2018
- ISO 10993-5:2009
- ISO 10993-10:2010
- EN 50360:2017
- EN 50566:2017
- EN 62479:2010