	<b>REC-73-8 Declaration of Conformity</b>	
	REC-73-8 Declaration of Conformity CardioWatch 287-1 20211116.docx	
	Based on: TEMPLATE REC-73-8 Declaration of Conformity v1.1	Author: Willem Baelde Date: 30-Aug-23

## *Declaration of Conformity*

Name of the Device: CardioWatch 287-1; Bracelet & Watch  
 Basic UDI-DI: 8720256776CW287-1C8  
 UMDNS classification: 13988 - Monitors, Physiologic, Electrocardiography, Telemetric  
 Risk class: IIa  
 Classification based on: Rules 10 & 11  
 Intended purpose:  
 The CardioWatch 287 is a wireless remote monitoring system 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 and sleep. Data is transmitted wirelessly from the device via the application or gateway to a health cloud where it is stored and made available for further analysis.

Place of issue: Den Haag, The Netherlands  
 Date of issue: November 16, 2021

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: DARE!! Services B.V.  
 Notified Body Address: Vijzelmolenlaan 7  
 3447 GX Woerden, The Netherlands  
 NB Identification number: 1912


Device is in conformity with:

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

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	