CERTIFICATE

EU Quality Management System Certificate – Annex IX

Conformity Assessment Based on a Quality Management System and on Assessment of Technical Documentation
Regulation 2017/745 on MEDICAL DEVICES

The certificate:	**20M00011CRT02**
issued by:	**Kiwa Dare B.V.** **Vijzelmolenlaan 7** **3447 GX Woerden** **The Netherlands**
to:	
Manufacturer	Corsano Healthcare B.V.
Address	Wilhelmina van Pruisenweg 35 2595 AN Den Haag
SRN:	NL-MF-000013825
EAR:	Not applicable Not applicable

The scope of certificate comprises an EU quality management system regarding the following devices or groups of devices: Hardware and associated software applications that utilise a photoplethysmogram to provide automated regular measurements of activity and vital signs in the area of health monitoring.

This certificate is based on the following documents:
Audit report: 20M00011RPT01
TD report: 21M00085RPT01

Kiwa Dare B.V. hereby declares that it has audited the quality assurance system in accordance with MDR Annex IX and that the relevant provisions of the Regulation 2017/745 dated May 5, 2017 concerning Medical Devices are fulfilled. The validity of this certificate is three years and includes the surveillance obligations of Annex IX, section 3. The products shown in the scope of certification are covered by this certificate and may bear the CE marking using the Notified Body number “1912”.

Issued for the first time:	**15-11-2021**	**Preceding certificates:**	**20M00011CRT01**
Reissued:	**25-04-2023**		
Valid to:	**15-11-2024**	**Date of identification of changes:**	**25-04-2023**

Kiwa Dare B.V.

N. Cuper Ph.D.
Certification decision maker

Ing. D. Van der Vlugt
Director

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Appendix of EU Quality Management System Certificate – Annex IX

Devices/groups of devices	Risk classification
CardioWatch 287-1 Z12040113 REGIONAL PLETHYSMOGRAPHS	Devices in Class IIa
CardioWatch 287-2 Z12040113 REGIONAL PLETHYSMOGRAPHS	Devices in Class IIa

The certificate: **20M00011CRT02**