



Quality Management System Certificate EN-ISO 13485:2016

The certificate: 22M00194CRT01

issued by: Kiwa Dare B.V.
Vijzelmolenlaan 7
3447 GX Woerden
The Netherlands

to:
Manufacturer TeMeCo B.V.
Address Stationsplein 99, unit 232
1703 WE Heerhugowaard
The Netherlands

Regarding the scope Design & Development, Production, Storage, Distribution, Installation, and Servicing of Ambulatory devices to be used to measure and record electrocardiogram (ECG) noninvasively.

This certificate is based on the following documents:
21M00198RPT01

Kiwa Dare B.V. hereby declares that it has audited the quality management system in accordance with EN-ISO 13485:2016 + AC:2018 and that all requirements of the standard and its implementation are fulfilled.

The validity of this certificate is three years and includes the surveillance obligations of EN-ISO 17021-1:2015.

Issued for the first time: 29-09-2022
Reissued: NA
Valid to: 29-09-2025

Kiwa Dare B.V.

Dr. Ir. W. Sjoerdsma
Certification decision maker

Ing. D. Van der Vlugt
Director