



CERTIFICATE

Quality Management System Certificate EN-ISO 13485:2016

The certificate : 22M00041CRT01

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

to:
Manufacturer Fysicon B.V.
Address Hoogheuvelstraat 114, 5349 BA Oss, The Netherlands

Regarding the scope: Design & Development, Production, Storage, Distribution, Installation, and Servicing of software and hardware systems for cardiology, radiology, image management and research for intra- and extramural healthcare.

This certificate is based on the following documents:
21M00066RPT02

Kiwa Dare B.V. hereby declares that it has audited the quality management system in accordance with EN-ISO 13485:2016 + AC:2018 + A11:2021 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: 03-03-2022
Reissued: NA
Valid to: 03-03-2025

Kiwa Dare B.V.

Dr. Ir. W. Sjoerdsma
Certification decision maker

Ing. D. Van der Vlugt
Director

Certificate number: 22M00041CRT01

