



## Quality Management System Certificate EN-ISO 13485:2016

The certificate: **24M00193CRT01**

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:**  
24M00192PRP02

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.

|                                   |                    |                  |           |
|-----------------------------------|--------------------|------------------|-----------|
| <b>Issued for the first time:</b> | <b>03-Mar-2022</b> | <b>Reissued:</b> | <b>NA</b> |
| <b>Re-certification:</b>          | <b>03-Mar-2025</b> |                  |           |
| <b>Valid to:</b>                  | <b>03-Mar-2028</b> |                  |           |

**Kiwa Dare B.V.**

DocuSigned by:  
*N. Vazirpanah*  
2942F7C5177B433...

Signed by:  
*Dennis van der Vlugt*  
4F831C843C0B4EA...

**Dr. N. Vazirpanah**  
Certification decision maker

**Ing. D. van der Vlugt**  
Director



# CERTIFICATE