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 : 21M00066CRT01

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
Single Registration Number
NL-MF-000002694

The scope of certificate comprises an EU quality management system regarding the following devices or groups of devices:
Vital signs monitoring system for application during surgical procedures.

This certificate is based on the following documents:
Audit report 21M00066RPT02
TD review report 21M00111RPT01

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: **14-03-2022**

Reissued: **NA**

Valid to: **14-03-2025**

Preceding certificates: DIRECTIVE 93/42/EEC, TUV Nord Cert, Germany. NB 0044. Cert. nr. 44 232 128018

Date of identification of changes: Issue date of Kiwa Dare certificate
Last device serial number covered by NB 0044: 076001A284
Serial Number of first device / UDI PI under NB 1912: 076001A285

Kiwa Dare B.V.

Dr.ir. W. Sjoerdsma
Certification decision maker

Ing. D. van der Vlugt
Director