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:	**24M00192CRT01**
issued by:	**Kiwa Dare B.V.** **Vijzelmolenlaan 7** **3447 GX Woerden** **The Netherlands**
to:	
Manufacturer	Fysicon B.V.
Address	Hoogheuvelstraat 11 5349 BA Oss The Netherlands
SRN:	NL-MF-000002694

The scope of certificate comprises an EU quality management system regarding the following devices or groups of devices: Polygraphy systems for haemodynamic studies

This certificate is based on the following documents:
Audit report: 24M00192PRP02
TD report: 24M00202RPT01

Kiwa Dare B.V. hereby declares that it has audited the quality assurance system in accordance with MDR Annex IX, chapter I and III 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 five 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-Mar-2022**	**Reissued:**	**NA**
Re-certification:	**14-Mar-2025**		
Valid to:	**14-Mar-2030**	**Preceding certificates:**	**21M00066CRT02**

Kiwa Dare B.V.

DocuSigned by:
N. Vazirpanah
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Dr. N. Vazirpanah
Certification decision maker

Signed by:
Dennis van der Vlugt
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Ing. D. van der Vlugt
Director

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Appendix of EU Quality Management System Certificate – Annex IX

Devices	Risk classification	Intended purpose (only IIb and III)
QMAPP 8719689142QMAPPQ8 Z12050702 - Polygraphy systems for haemodynamic studies	Devices in Class IIb	QMAPP is intended to be used by professional healthcare providers for physiological/hemodynamic monitoring. The system may be used to display and analyse surface ECG (Electro Cardio Gram); respiration rate; invasive pressures; pulse oximetry (SpO2); End tidal CO2 (EtCO2); fractional flow reserve (FFR); non-invasive blood pressure (NiBP); surface body temperature;, cardiac output and intracardiac ECG. QMAPP provides also clinical data acquisition, medical image/data processing and analytical assessment. QMAPP has an alarm function for environments of use where the patient is continuously attended by a clinical operator. QMAPP is intended for use in the areas of, but not limited to, cardiology; cardiac catheterization; electrophysiology; radiology and invasive radiology.

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