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QUALITY MANAGEMENT SYSTEM

EU-CERTIFICATE

Regulation (EU) 2017/745

Manufacturer:	PulseOn Oy Tekniikantie 12 FI-02150 Espoo Finland
Single registration number:	FI-MF-000009325
Conformity assessment procedure:	Regulation (EU) 2017/745 Annex IX
Device category:	MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters
Date of expiry:	25 February 2027

The manufacturer's quality management system covering the device category has been assessed and approved in accordance with the Annex IX to Regulation (EU) 2017/745. Approval shall be valid until the expiry date provided that the manufacturer fulfills the obligations imposed by Annex IX in Regulation. The products covered by the certificate and the details related to the maintenance of this certificate are specified in the attachment(s) to the certificate.

Date of issue: 25 February 2022

EUROFINS EXPERT SERVICES OY

Aliina Nieminen

Satu Rajala

Certificate no:

CR-03-1224-781-22

Notified Body no. 0537:
Eurofins Expert Services Oy
Kivimiehentie 4
02151 Espoo, FINLAND

Information about the examinations and tests as per MDR Annex XII, section 10, is available upon request from EES-medical@eurofins.fi.

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Attachment 1 to the certificate no: CR-03-1224-781-22

Manufacturer:	PulseOn Oy Tekniikantie 12 FI-02150 Espoo Finland
Other sites covered by the quality management system:	-
Single registration number:	FI-MF-000009325
Conformity assessment procedure:	Regulation (EU) 2017/745 Annex IX
Limitations to the validity of the certificate:	No limitations

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The certificate covers the following products:

MD-codes:	MDA 0203 MDS 1009, MDS 1010 MDT 2010, MDT 2011	
Device category:	MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	
Product name	*Product details*	
PulseOn Arrhythmia Monitor System	Model	AMS-1
	Nomenclature code	C020599
	Risk class	IIa

The validity and maintenance of this certificate require the surveillance performed by the notified body in accordance with the MDR Annex IX (3). The surveillance includes annual quality management system audits at the manufacturer's premises as well as regular unannounced audits. If necessary, all audits may be carried out at the premises of the manufacturer's suppliers and/or subcontractors. The surveillance also includes the assessment of the significant changes planned by the manufacturer and the assessment of the technical documentation in accordance with the notified body's sampling plan (IIa and IIb).

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Attachment 1 to the certificate no: CR-03-1224-781-22

Date of issue of this attachment: 25 February 2022

EUROFINS EXPERT SERVICES OY

Aliina Nieminen Satu Rajala

Change history of the certificate:				
Certificate no	**Revision**	**Status of the certificate**	**Date of issue**	**Description of the change**
CR-03-1224-781-22	01	Initial certification	25.2.2022	Initial revision