

QUALITY MANAGEMENT SYSTEM

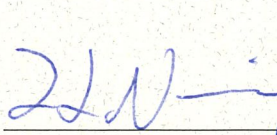
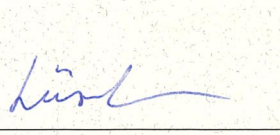
EU-CERTIFICATE

Regulation (EU) 2017/745

Manufacturer:	Movesense Oy Tammiston kauppatie 7A FI-01510 Vantaa Finland
Single registration number:	FI-MF-000024281
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:	6 April 2028

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 to the certificate.

Date of issue: 6 April 2023

		
Aliina Nieminen		Liisa-Ida Sorsa
Certificate no:		Notified Body no. 0537:
CR-03-1229-813-23		Eurofins Electric & Electronics Finland Oy
		Kivimiehentie 4
		FI-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.

Attachment 1 to the certificate no: CR-03-1229-813-23

Manufacturer:	Movesense Oy Tammiston kauppatie 7A FI-01510 Vantaa Finland	
Other sites covered by the quality management system:	-	
Single registration number:	FI-MF-000024281	
Conformity assessment procedure:	Regulation (EU) 2017/745 Annex IX	
Limitations to the validity of the certificate:	No limitations	

The certificate covers the following products:

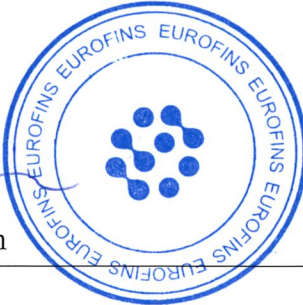
MD-codes:	MDA 0203 MDS 1009 MDT 2010, 2011	
Device category:	MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	
<i>Product name</i>	<i>Product details</i>	
Movesense MD	Model	-
	Nomenclature code	C900300 Cardiovascular sensors – other
	Risk class	IIa

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).

Attachment 1 to the certificate no: CR-03-1229-813-23

Date of issue of this attachment: 6 April 2023


Aliina Nieminen


Liisa-Ida Sorsa

Change history of the certificate:				
Certificate no	Revision	Status of the certificate	Date of issue	Description of the change
CR-03-1229-813-23	01	Initial certification	6.4.2023	Initial revision