QUALITY MANAGEMENT SYSTEM

EU-CERTIFICATE

Regulation (EU) 2017/745

Manufacturer:	TidalSense Limited The Vinery, 15a Vinery Road CB1 3DN Cambridge United Kingdom
Single registration number:	GB-MF-000035597
Conformity assessment procedure:	Regulation (EU) 2017/745 Annex IX
Device category:	MDA 0315 Software
Date of expiry:	11 March 2030

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: 11 March 2025

Satu Rajala

Liisa-Ida Sorsa

Certificate no:

CR-03-1248-866-25

Notified Body no. 0537:
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 finland_medical@cpt.eurofinseu.com.

Attachment 1 to the certificate no: CR-03-1248-866-25

Manufacturer:	TidalSense Limited The Vinery, 15a Vinery Road CB1 3DN Cambridge United Kingdom Authorised representative: Donawa Lifescience Consulting Srl Piazza Albania 10 00153 Rome Italy
Other sites covered by the quality management system:	N/A
Single registration number:	GB-MF-000035597
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 0315 MDT 2010, MDT 2011	
Device category:	MDA 0315 Software	
Product name	*Product details*	
N-Tidal Diagnose 1	Model	v1.0
	Nomenclature code	Z12159092 – Various pneumology and respiratory physiopathology instruments – medical device software
	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-03-1248-866-25

Date of issue of this attachment: 11 March 2025

Satu Rajala

Liisa-Ida Sorsa

Change history of the certificate:				
Certificate no	**Revision**	**Status of the certificate**	**Date of issue**	**Description of the change**
CR-03-1248-866-25	01	Initial certification	11 March 2025	Initial revision