

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

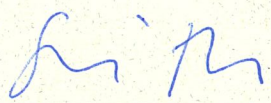
Conformity assessment procedure: Regulation (EU) 2017/745 Annex IX

Device category: MDA 0315 Software


Date of expiry: 11 March 2030

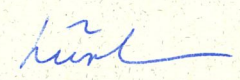
The manufacturer's quality management system covering the device category has been assessed and approved in accordance with the Annex IX to Regulation (EU) 2017/745. Approval shall be valid until the expiry date provided that the manufacturer fulfills the obligations imposed by Annex IX in Regulation. 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	
<i>Product name</i>	<i>Product details</i>	
N-Tidal Diagnose 1	Model	v1.0
	Nomenclature code	Z12159092 – Various pneumology and respiratory physiopathology instruments – medical device software
	Risk class	Ila

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