

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
C716580

Initial certification date:  
17 November 2025

Valid:  
17 November 2025 – 16 November 2028

This is to certify that the management system of

## **SMARTHEN SL**

CALLE VIERA Y CLAVIJO, NUM 30, PLANTA 2, 35002, LAS PALMAS DE GRAN CANARIA,  
Spain

has been found to conform to the Quality Management System standard:

### **ISO 13485:2016 / EN ISO 13485:2016**

This certificate is valid for the following scope:

**Design & development, manufacturing, distribution and sales of general active non-implantable medical device for enteral feeding and digital solutions for remote health monitoring.**

Place and date:  
Høvik, 17 November 2025



For the issuing office:  
DNV Product Assurance AS  
Veritasveien 1, 1363 Høvik, Norway

*Cecilie Gudesen Torp*

Cecilie Gudesen Torp  
Management Representative