

## **Quality System Certificate**



Certificate No.: DGM - 815

Reference: aur2a2011v320f531

Date of issue: **2021-09-13** 

Valid Until: 2024-03-12

Initial date of issue: 2013-12-20

This is to certify that the quality system of:

ApodanNordic A/S Lyngsø Allé 3 2970 Hørsholm

fulfills the requirements in:

**DS/EN ISO 13485:2016** 

The certificate covers the following activities:

Manufacture and sales of wound care, hygiene- and disinfection products and related accessories to medical devices. Sales and service of compression systems

The certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. Certifications to DS/EN ISO 13485:2012, EN ISO 13485:2012, ISO 13485:2013, DS/EN ISO 13485:2016, EN ISO 13485:2016, ISO 13485:2016, DS/EN ISO 9001: 2015, EN ISO 9001:2015, and ISO 9001:2015 include the requirements of any applicable corrigendum. The quality system certificate is issued pursuant to Presafe Denmark A/S' terms and conditions for the certification of quality systems for medical devices.

Presafe Denmark A/S

Notified Body, Identification No. 0543 Tuborg Parkvej 8, 2900 Hellerup, Denmark Zeshaan Sayd authorized person

For Presafe Denmark A/S