

# Quality System Certificate

Certificate No.:  
**DGM – 840**

Reference:  
**Aur2a2302v320f810**

Date of issue:  
**2023-05-26**

Valid Until:  
**2026-05-26**

Initial date of issue:  
**2014-07-09**

This is to certify that the quality system of:

**Vigmed AB**  
**Kungsgatan 6**  
**252 21 Helsingborg**  
**Sweden**

fulfills the requirements in:

**EN ISO 13485:2016 + AC:2016 and EN ISO 9001:2015**

The certificate covers the following activities:

**Development and manufacturing of single use medical devices for preventing needle stick injuries**

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 13485:2003, 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