

Quality System Certificate

Certificate No.:
DGM – 840

Reference:
Aur2a2003v290f810

Date of issue:
2020-07-06

Valid Until:
2023-06-12

Initial date of issue:
2014-07-09

This is to certify that the quality system of:

Vigmed AB
Kungsgatan 6
252 21 Helsingborg
Sweden

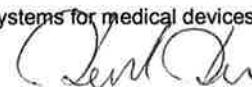
fulfills the requirements in:

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

Bent Buus
Authorized person

For Presafe Denmark A/S