



# Quality System Certificate

Certificate Number: DGM – 909

This is to certify that the quality system of:

## HB Medical Falster A/S

Ankervej 1  
4800 Nykøbing Falster  
Denmark

fulfills the requirements in:

## EN ISO 13485:2016

The certificate covers the following activities:

**Production, filling, labelling and packaging of non-sterile formulations of Medical devices: Solutions, suspensions, emulsions, creams, ointments and related products and packaging of In Vitro Diagnostic Medical Devices**

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: 2008, EN ISO 9001:2008, ISO 9001:2008 and ISO 9001:2015 include the requirements of the applicable corrigenda. The quality system certificate is issued pursuant to Presafe Denmark A/S' terms and conditions for the certification of quality systems for medical devices.

**Bent Buus**

Authorized person

For Presafe Denmark A/S

Date of issue: 2018-04-06  
Expires: 2021-04-06  
Initial date of issue: 2018-04-06  
Reference: aur1iso1802v30f846

### Presafe Denmark A/S

Tuborg Parkvej 8  
2900 Hellerup  
Denmark

