



# Quality System Certificate

Certificate Number: DGM – 728

This is to certify that the quality system of:

## SP Medical A/S

Møllevej 1  
4653 Karise  
Denmark

fulfills the requirements in:

## DS/EN ISO 13485:2012 & DS/EN ISO 9001:2008

The certificate covers the following activities:

**Development and manufacture of Guide Wires.  
Construction, production, assembly and decoration of  
injection moulded plastic parts and metal parts**

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 9001: 2008, EN ISO 9001:2008 and ISO 9001:2008 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.

  
**Heidi Jørgensen**  
Authorized person  
For Presafe Denmark A/S

Date of issue: 2015-11-04  
Expires: 2018-11-05  
Initial date of issue: 2011-05-11  
Reference: aur2a1508v130f766

### Presafe Denmark A/S

Tuborg Parkvej 8  
2900 Hellerup  
Denmark



Additional site covered by the certificate:

**SP Medical Sp. z o.o.**  
**Ul. Ceramiczna 2**  
**98-220 Zduńska Wola**  
**Poland**

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