



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 13485:2016

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 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.


Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue: 2018-11-06
Expires: 2021-11-06
Initial date of issue: 2011-05-11
Reference: aur2a1809v270f766

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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