

Quality System Certificate

Certificate No.:
DGM – 728

Reference:
aur2a1901v281f766

Date of issue:
2019-04-03

Valid Until:
2021-11-06

Initial date of issue:
2011-05-11

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:

Design and development, production, trade and distribution of medical devices made of metal, alloy, and plastics. Production, filling, assembly, packaging, coating and decoration of injection molded plastic and metal parts to be used for 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 9001:2015, 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



Heidi Jørgensen
Authorized person

For Presafe Denmark A/S



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Additional site(s) covered by the certificate:

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