

Quality System Certificate

Certificate No.:
DGM – 917

Reference:
aur2a1901v80f699

Date of issue:
2019-03-22

Valid Until:
2021-10-12

Initial date of issue:
2018-10-12

This is to certify that the quality system of:

Rønvig Dental Manufacturing A/S
Gl. Vejlevej 59
8721 Daugaard
Denmark

fulfills the requirements in:

EN ISO 13485:2016

The certificate covers the following activities:

**Development, production, servicing and marketing of dental products
and electro-medical equipment**

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