

Quality System Certificate

Certificate No.:
DGM – 641

Reference:
aur1iso2005v210f686

Date of issue:
2020-06-22

Valid Until:
2023-06-26

Initial date of issue:
2008-09-24

This is to certify that the quality system of:

Knudsen Plast A/S
Industrivej 21
3300 Frederiksværk
Denmark

fulfills the requirements in:

DS/EN ISO 13485:2016

The certificate covers the following activities:

Development of injection moulds, Injection moulding of plastic products, Assembly of injection moulded plastic products and Sterile packaging for the medical device industry.

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:

Knudsen Plast s.r.o..
Herl'anska 547,
093 03 Vranov nad Topl'ou,
Slovakia