



Quality System Certificate

Certificate Number: DGM – 641

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

Additional site covered by the certificate:

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

The certificate covers the following activities:

Contract design and development including development of injection moulds; production, assembly and sterile packaging of injection moulded plastic products 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: 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

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Presafe Denmark A/S

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