



# Quality System Certificate

Certificate No.:  
**DGM – 817**

Reference:  
**aur2a1903v870f422**

Date of issue:  
**2019-03-29**

Valid Until:  
**2020-03-06**

Initial date of issue:  
**2014-01-17**

This is to certify that the quality system of:

**DeRoyal Industries, Inc.**  
**200 DeBusk Lane**  
**Powell, TN 37849**  
**USA**

fulfills the requirements in:

**ISO 13485:2016**

The certificate covers the following activities:

**The design and manufacture of injection molded 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 9001:2015, 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

**Bent Buus**  
Authorized person

For Presafe Denmark A/S



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Additional site(s) covered by the certificate:

Hospital Disposables  
104 Wheeler Street  
Portland, TN 37148  
United States of America

Royal Precision Plastics  
300 DeBusk Lane  
Powell, TN 37849  
United States of America

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