

# Quality System Certificate

Certificate No.:  
**DGM – 537**

Reference:  
**aur1i2401v281f424**

Date of issue:  
**2024-02-02**

Valid Until:  
**2025-02-25**

Initial date of issue:  
**2006-02-03**

This is to certify that the quality system of:

**Royal Sterilization Systems**  
**A division of DeRoyal Industries, Inc.**  
**1135 Highway 33 South**  
**New Tazewell, TN 37825**  
**USA**

fulfills the requirements in:

**ISO 13485:2016**

The certificate covers the following activities:

**Ethylene oxide sterilization of medical devices and laboratory services  
for chemistry, microbiology, sterility and media preparation**

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 13485:2016, 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

  
**Zeshaan Sayd**  
Authorized person

For Presafe Denmark A/S



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Additional site(s) covered by the certificate:

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Royal Sterilization Systems  
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1211 Highway 33 South  
New Tazewell, TN 37825  
USA