



# Quality System Certificate

Certificate Number: DGM – 537

This is to certify that the quality system of:

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

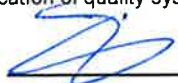
fulfills the requirements in:

**DS/EN ISO 13485:2003**

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 13485:2012, EN ISO 13485:2012, ISO 13485:2003, 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.

  
**Carsten Worm Jensen**  
Authorized person

For Presafe Denmark A/S

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**Presafe Denmark A/S**

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