



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, TN 37825
USA

fulfills the requirements in:

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 13485:2016, EN ISO 13485:2016, ISO 13485:2016, DS/EN ISO 9001: 2008, EN ISO 9001:2008, ISO 9001:2008 and ISO 9001:2015 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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