



Quality System Certificate

Certificate Number: DGM – 684

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:

EN ISO 11135:2014

The certificate covers the following activities:

Ethylene oxide sterilization of medical devices

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

Tuborg Parkvej 8
2900 Hellerup
Denmark

DGM