

Quality System Certificate

Certificate No.:
DGM – 684

Reference:
aur1i2401v281f424

Date of issue:
2024-02-02

Valid Until:
2025-02-25

Initial date of issue:
2009-04-30

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 13485:2016, 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:

Royal Sterilization Systems
A division of DeRoyal Industries, Inc.
1211 Highway 33 South
New Tazewell, TN 37825
USA