

Quality System Certificate

Certificate No.:
DGM – 537

Reference:
aur1i2012v240f424

Date of issue:
2020-12-28

Valid Until:
2022-03-05

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


Heidi Jørgensen
Authorized person

For Presafe Denmark A/S