Quality System Certificate

Presafe®
A DNV & NEMKO COMPANY

Certificate Number: DGM – 817

This is to certify that the quality system of:

DeRoyal Industries, Inc.

200 DeBusk Lane
Powell, TN 37849
USA

fulfills the requirements in:

ISO 13485:2003

The certificate covers the following activities:

The design and manufacture of injection molded products for the medical device industry

COPY

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.

Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue:	2017-03-06
Expires:	2019-03-31
Initial date of issue:	2014-01-17
Reference:	aur2a1701v640f422

DANAK
SYSTEM Reg. No. 5007

Presafe Denmark A/S
Tuborg Parkvej 8
2900 Hellerup
Denmark

DGM

© DGM 2013-08-15
BL 11 0-014E v17 0

Presafe®
A DNV & NEMKO COMPANY

Only site covered by the certificate:

Hospital Disposables
104 Wheeler Street
Portland, TN 37148
United States of America

COPY

Certificate number:	DGM – 817	Date of issue:	2017-03-06
Certificate type:	Quality System Certificate	Expires:	2019-03-31
		Initial date of issue:	2014-01-17
		Reference:	aur2a1701v640f422

Presafe Denmark A/S
Tuborg Parkvej 8
2900 Hellerup
Denmark

DANAK
SYSTEM Reg. No. 5007

DGM

© DGM 2013-08-15
BL 11.0-014E v17.0