

This is to certify that the quality system of:

DeRoyal Industries, Inc.
200 DeBusk Lane
Powell, TN 37849
USA

has been approved in conformity with the requirements of

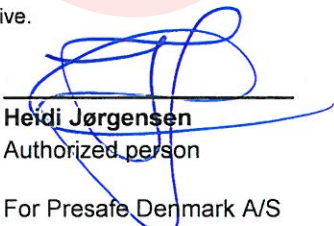
Annex V, section 3.2 - Production quality assurance

of Council Directive 93/42/EEC concerning medical devices as transposed into Danish law.

The certificate covers the following activities:

Manufacture and final inspection of wound lavage system in class IIa, Eye Spear medical sponges in class Is and sensostrip forehead thermometers in class Im.

The EC 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. This EC certificate is issued pursuant to the Presafe Denmark A/S terms and conditions for the certification of medical devices and entitles the manufacturer to affix the CE mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits as per the Directive.


Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue: 2017-06-23
Expires: 2019-08-07
Initial date of issue: 2014-10-09
Reference: Aur5a1706v731f422

Presafe Denmark A/S

Notified Body, Identification No. 0543

Tuborg Parkvej 8, 2900 Hellerup, Denmark

The authorized EC representative:

QNET BV

**Hommerterweg 286
6436 AM Amstenrade
The Netherlands**

COPY

Certificate number: DGM – 846
Certificate type: EC Certificate

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