



Quality System Certificate

Certificate Number: DGM – 860

This is to certify that the quality system of:

Medichanical Engineering ApS

Havneparken 2
7100 Vejle
Denmark

fulfills the requirements in:

DS/EN ISO 9001:2008 and DS/EN ISO 13485:2012

The certificate covers the following activities:

Manufacturing of orthopedic surgical measuring devices for non-vital physiological parameters in Class Im and Class IIa.

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: 2015-10-09
Expires: 2018-10-09
Initial date of issue: 2015-10-09
Reference: aur5a1507v31f825

Presafe Denmark A/S

Tuborg Parkvej 8
2900 Hellerup
Denmark



Additional sites covered by the certificate:

Klokkestøbergade 17, st. 8,

9000 Aalborg

Denmark

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