

This is to certify that the quality system of:

**Medichanical Engineering ApS**  
**Havneparken 2**  
**7100 Vejle**  
**Denmark**

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:

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

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: 2015-10-09  
Expires: 2020-10-09  
Initial date of issue: 2015-10-09  
Reference: aur5a1507v31f825

**Presafe Denmark A/S**

*Notified Body, Identification No. 0543*  
Tuborg Parkvej 8, 2900 Hellerup, Denmark

Additional sites covered by the certificate:

**Klokkestøbergade 17, st. 8,**

**9000 Aalborg**

**Denmark**

Certificate number: DGM – 861  
Certificate type: EC Certificate

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