

# Quality System Certificate

Certificate No.:  
**DGM – 860**

Reference:  
**aur5a2104v131f825**

Date of issue:  
**2021-06-17**

Valid Until:  
**2024-06-17**

Initial date of issue:  
**2018-08-28**

This is to certify that the quality system of:

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

fulfills the requirements in:

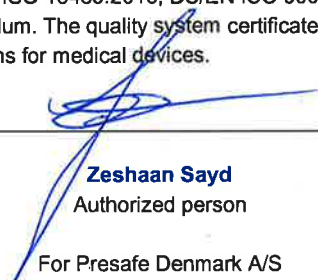
**DS/EN ISO 13485:2016**

The certificate covers the following activities:

**Manufacturing and servicing of orthopedic surgical measuring devices  
for non-vital physiological parameters.**

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

  
**Zeshaan Sayd**  
Authorized person  
For Presafe Denmark A/S

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Additional site(s) covered by the certificate:

Klokkestøbergade 17, st. 8,  
9000 Aalborg  
Denmark