



# Quality System Certificate

Certificate Number: DGM – 831

This is to certify that the quality system of:

## Nidacon International AB

Fløjelsberggatan 16B

431 37 Mölndal

Sweden

fulfills the requirements in:

## EN ISO 13485:2016

The certificate covers the following activities:

**Design, development, manufacture, sales and marketing of medical devices for ART (Assisted Reproduction Technology)**

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: 2008, EN ISO 9001:2008, ISO 9001:2008 and ISO 9001:2015 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

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### Presafe Denmark A/S

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