

Quality System Certificate

Certificate No.:
DGM – 770

Reference:
Aur5a1809v200f731

Date of issue:
2019-01-18

Valid Until:
2022-01-18

Initial date of issue:
2011-12-12

This is to certify that the quality system of:

Nunc A/S
Kamstrupvej 90
4000 Roskilde
Denmark
(Thermo Fisher Scientific, Roskilde Site)

fulfills the requirements in:

DS/EN ISO 13485:2016

The certificate covers the following activities:

Development, manufacture, and sterilization by irradiation medical devices for In Vitro Fertilization and storage and transport tubes and containers for In Vitro Diagnostic Use. Sub-contact irradiation of customer products to customer specification per. ISO 11137.

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



Heidi Jørgensen
Authorized person

For Presafe Denmark A/S