

Quality System Certificate

Certificate No.:
DGM – 916

Reference:
aur5a2201v340f731

Date of issue:
2022-03-14

Valid Until:
2025-03-14

Initial date of issue:
2018-09-14

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:

EN ISO 9001:2015

The certificate covers the following activities:

Development, manufacture and sterilization by irradiation of Laboratory plastic equipment. Sub-contract irradiation of customer products to customers 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


Zeshaan Sayd
Authorized person

For Presafe Denmark A/S