

Quality System Certificate

Certificate No.:
DGM – 911

Reference:
auriso2111v70f847

Date of issue:
2021-12-14

Valid Until:
2024-03-25

Initial date of issue:
2018-06-29

This is to certify that the quality system of:

LGC Biosearch Technologies A/S
Voldbjergvej 16
8240 Risskov
Denmark

fulfills the requirements in:


ISO 13485:2016

The certificate covers the following activities:

**Contract manufacturer of synthetic oligonucleotides in support of
molecular In-Vitro diagnostics and related industries**

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

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Additional site(s) covered by the certificate:

LGC Biosearch Technologies A/S
Sønderskovvej 5
8520 Lystrup
Denmark