

Quality System Certificate

Certificate No.:
DGM – 928

Reference:
auriso2004v22f856

Date of issue:
2020-10-13

Valid Until:
2023-11-03

Initial date of issue:
2019-07-19

This is to certify that the quality system of:

Actim Oy
Klovinpellontie 3
02180 Espoo
Finland

fulfills the requirements in:

ISO 13485:2016
EN ISO 13485:2016

The certificate covers the following activities:

The design and development, manufacture, distribution and service, of in-vitro diagnostic analyzers, in-vitro diagnostic test kits, controls and reagents used in diagnosis and screening of pregnancy, disease status, and endocrine disorders, including near patient in-vitro diagnostic devices

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:

**Noljakantie 13
80130 Joensuu
Finland**