



# Quality System Certificate



Certificate No.:  
**DGM – 543**

Reference:  
**auriso1905v190f529**

Date of issue:  
**2019-07-19**

Valid Until:  
**2020-11-03**

Initial date of issue:  
**2006-02-24**

This is to certify that the quality system of:

**Oy Medix Biochemica Ab**  
**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 and distribution of reagents  
used in in-vitro diagnostic devices and controls**

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

**Henrik Tønsberg**  
Authorized person

For Presafe Denmark A/S



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Additional site(s) covered by the certificate:

**Noljakantie 13  
80130 Joensuu  
Finland**