Quality System Certificate

Certificate Number: DGM – 543

A DNV & NEMKO COMPANY

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, 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: 2008, EN ISO 9001:2008 and ISO 9001:2008 include the requirements of the applicable corrigenda. The quality system certificate is issued pursuant to Presafe Denmark A/S' terms and conditions for the certification of quality systems for medical devices.

Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue:	2017-10-30
Expires:	2020-11-03
Initial date of issue:	2006-02-24
Reference:	auriso1708v151f529

DANAK
SYSTEM Reg. No. 5007

Presafe Denmark A/S
Tuborg Parkvej 8
2900 Hellerup
Denmark

DGM

Presafe®
A DNV & NEMKO COMPANY

Additional sites covered by the certificate:

Noljakantie 13
80130 Joensuu
Finland

Certificate number:	DGM – 543	Date of issue:	2017-10-30
Certificate type:	Quality System Certificate	Expires:	2020-11-03
		Initial date of issue:	2006-02-24
		Reference:	auriso1708v151f529

Presafe Denmark A/S
Tuborg Parkvej 8
2900 Hellerup
Denmark

DANAK
SYSTEM Reg. No. 5007

DGM