Presafe®
A DNV GL COMPANY

Quality System Certificate

DANAK
SYSTEM Reg. No. 5007

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 543	auriso2004v211f529	2020-10-13	2023-11-03	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

Heidi Jørgensen
Authorized person

For Presafe Denmark A/S