

QUALITY SYSTEM

CERTIFICATE

ISO 13485:2016

Oy Reagena Ltd

Takojantie 18, 70900 Toivala Finland

Eurofins Expert Services Oy has assessed the company's quality system and found that it meets the requirements of ISO 13485:2016.

This certificate covers the following functions/services:

Design, development, production, marketing and distribution of zoonotic infections and immunity diagnostic test kits, and staining reagents. Outsourced manufacturing of rapid test reader. Distributor of in vitro diagnostic products for medical laboratories.

Issued:

17th April, 2020

Valid until:

17th April, 2023

First issued: 17th April, 2020

Mari Ulmanen

Certifier

Eurofins Expert Services Oy

Elina Tuomola

Lead Auditor

Eurofins Expert Services Oy

Certificate nr.

EUFI29-19005853-S1

FINAS
Finnish Accreditation Service
S021 (EN ISO/IEC 17021-1)

Certification body: Eurofins Expert Services Oy Kivimiehentie 4 FI-02151 Espoo, FINLAND