

## QUALITY SYSTEM

## CERTIFICATE

ISO 13485:2016

Reagena Oy

Takojantie 18, 70900 Toivala Finland

Eurofins Electric & Electronics Finland 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, manufacturing, marketing, sales and servicing of in vitro diagnostic tests, test kits, reagents and instruments used in diagnosis and monitoring of diseases related to infection and immunity. Distribution of in vitro diagnostic products for medical laboratories.

Valid from:

17 April, 2023

Valid until: 17 April, 2026

First issued: 17 April, 2020

Aliisa Siljander Decision Maker

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

Certificate nr. EUFI29-23000028-S1



Riikka Kylväjä Lead Auditor

Certification body: Eurofins Electric & Electronics Finland Oy Kivimiehentie 4 FI-02150 ESPOO, FINLAND