

QUALITY SYSTEM

CERTIFICATE

ISO 13485:2016

Actim OyKlovinpellontie 3, FI-02180 Espoo
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, distribution and servicing of in vitro diagnostic medical device reagents, kits, controls and instruments used in diagnosis, monitoring and screening of pregnancy, disease status, infectious diseases and endocrine disorders, including devices for near-patient testing.

Valid from:
2 July, 2024

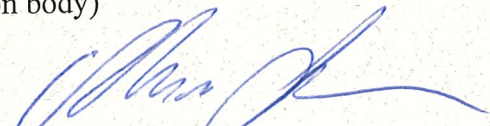
Valid until:
2 July, 2027

First issued:
19 July, 2019

(before 02.07.2021, the certificate
was issued by another certification body)



Satu Rajala
Decision Maker





Aliisa Siljander
Lead Auditor

Certificate nr.
EUFI29-24000274-S



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

Annex to the Certificate EUFI29-24000274-S

Organisation:	Actim Oy Klovinpellontie 3, FI-02180 Espoo Finland
The scope of the certification includes the following sites	
Site 1	<p>Actim Oy Klovinpellontie 3, FI-02180 Espoo Finland</p> <p><u>Site scope:</u> Design and development of in vitro diagnostic medical device reagents, kits, controls and instruments, and manufacturing of in vitro diagnostic medical device controls, used in diagnosis, monitoring and screening of pregnancy, disease status, infectious diseases and endocrine disorders, including devices for near-patient testing.</p>
Site 2	<p>Actim Oy Noljakantie 13, FI-80130 Joensuu Finland</p> <p><u>Site scope:</u> Manufacturing of in vitro diagnostic medical device reagents and kits, distribution of in vitro diagnostic medical device reagents, kits, controls and instruments, and servicing of in vitro diagnostic instruments, used in diagnosis, monitoring and screening of pregnancy, disease status, infectious diseases and endocrine disorders, including devices for near-patient testing.</p>
Date:	<p>Valid from: 2 July 2024</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  Satu Rajala </div> <div style="text-align: center;">  Aliisa Siljander </div> </div>