CERTIFICATE

This is to certify that the company

Actim Oy

Klovinpellontie 3
02180 Espoo
Finland

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:
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.
- AUS (a), BRA, CND, JPN, USA (a, b, c, d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	549308 MDSAP16
Certificate unique ID	1000169254
Effective date	2024-08-17
Expiry date	2027-08-16
Frankfurt am Main	2024-07-05

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, info-med@dqs.de
DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit https://www.dqs.de/en/customer-database/ to validate this certificate.
The validity of this certificate can only be verified by the QR-code.

413.01 Version 6.0

Annex to certificate
Certificate registration No.: 549308 MDSAP16
Certificate unique ID: 1000169254
Effective date: 2024-08-17

Actim Oy

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Finland

Audited site	REPs FEI No.: site scope and country-specific requirements
549309 **Actim Oy** Klovinpellontie 3 02180 Espoo Finland	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. **- AUS (a), BRA, CND, JPN, USA (a, b, c, d)** **REPs FEI No: F005684**
549310 **Actim Oy** Noljakantie 13 80130 Joensuu Finland	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. **- AUS (a), BRA, CND, JPN, USA (a, b, c, d)** **REPs FEI No.: F005685**

Annex to certificate
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02180 Espoo
Finland

Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821