



Declaration of Conformity

Manufacturer **Actim Oy**
Klovinpellontie 3, FI-02180, Espoo
Finland

IVD product **Actim® Ingeni** (product code 19101AC)

We hereby declare that the above mentioned device complies with the requirements of

98/79/EC In Vitro Diagnostic Medical Devices Directive (IVD Directive)
Finnish National Act 629/2010
2014/35/EC The Low Voltage Directive (LVD)
2011/65/EU + 2015/863/EU + 2017/2102/EU The Restriction of Hazardous Substances Directive (RoHS)

and to the following standards

Standards **SFS-EN ISO 13485:2016, AC 2016, AC 2018**
Medical devices - Quality Management Systems - Requirement for the regulatory purposes.

SFS-EN ISO 14971: 2019
Medical Devices. Application of risk management to medical devices.

ISO 15223-1:2021
Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

ISO 15223-2:2010
Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation.

SFS-EN ISO 18113-1:2012
In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.

SFS-EN ISO 18113-3:2012
In vitro diagnostic medical devices -Information supplied by the manufacturer (labelling). Part 3: In vitro diagnostic instruments for professional use

SFS-EN 61010-1:2011
Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

SFS-EN 61010-2-101:2017
Safety requirements for electrical equipment for measurement, control, and laboratory use - Particular requirements for in vitro diagnostic medical equipment

SFS-EN 61326-2-6:2013
Electrical equipment for measurement, control and laboratory use - EMC requirements - Particular requirements - In vitro diagnostic medical equipment

SFS-EN 62366-1:2015/A1:2020:en
Medical devices - Part 1: Application of usability engineering to medical devices

IVDD
classification

General class

In Espoo 16th of December 2021


Magnus Pålsson
Managing Director

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