Declaration of Conformity

Manufacturer

Actim Oy
Klovinpellontie 3, FI-02180, Espoo
Finland

IVD product

Actim® 1ngeni (product code 19100AC)

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)
20114/30/EC The Electromagnetic Combability Directive (EMC)
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: 2012
Medical Devices. Application of risk management to medical devices.

ISO 15223-1:2016
Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied 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, AC:2016
Medical devices - Part 1: Application of usability engineering to medical devices

IVDD classification

General class

In Espoo 14th of May 2020

Sinikka Tiisala
Vice-President
Diagnostic tests Business Unit