Declaration of Conformity

Manufacturer

Actim Oy
Klovinpellontie 3, FI-02180, Espoo
Finland

IVD product

Actim® ELISA SARS-CoV-2 IgG (Product code 35530ETAC)

We hereby declare that the above mentioned device complies with the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices (IVD Directive) and the corresponding Finnish National Act 629/2010 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.
SFS-EN 13612:2002 + AC
Performance evaluation of *in vitro* diagnostic medical devices.
SFS-EN ISO 23640:2015 (ISO 23640:2011)
In vitro diagnostic medical devices. Evaluation of stability of *in vitro* diagnostic reagents.
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 18113-2:2012
In vitro diagnostic medical devices -Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use.

IVDD classification

General class

In Espoo 4th of January 2021

Sinikka Tiisala
Vice-President
Diagnostic tests Business Unit