



Declaration of Conformity

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

IVD product **Actim® Partus Controls** (Product code 31900ETAC)

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

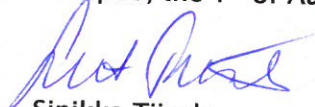
Standards

- 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.
- SFS-EN 13975:2003**
Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects

IVDD
classification

General class

In Espoo, the 1st of August 2019


Sinikka Tiisala
Business Director

Actim Oy - A subsidiary of Medix Biochemica

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