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