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  
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.
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.
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

General class

In Espoo, the 1st of August 2019

Sinikka Tilsala  
Business Director