Declaration of Conformity

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

IVD product
Actim® Pancreatitis (Product code 32731ETAC and 32732ETAC)

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

IVDD classification
General class

In Espoo, the 28th of June 2019

Sinikka Tiitala
Business Director

Actim Oy - A subsidiary of Medix Biochemica

HEADQUARTERS
Klovinpellontie 3
FI-02180 Espoo, Finland

MANUFACTURING SITE
Noljakantie 13
FI-80130 Joensuu, Finland

tel: +358 0 20 645 3040
fax: +358 0 20 645 3050
medix@medixbiochemica.com
www.medixbiochemica.com
VAT reg. no. FI29540422