Declaration of Conformity

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

IVD product  
Actim® Pancreatitis Controls (Product code 32700ETAC)

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

  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.
  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 1st of August 2019

Sinikka Tilsala  
Business Director

Actim Oy - A subsidiary of Medix Biochemica

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