Declaration of Conformity

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

IVD product: Actim® PROM Controls (Product code 30800ETAC)

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 - Quality Management Systems - Requirement for the regulatory purposes.
- 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 Tiisala
Business Director

Actim Oy - A subsidiary of Medix Biochemica

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