Declaration of Conformity

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

IVD product: Actim® PROM (Product code 30830ETAC, 30831ETAC, 30832ETAC)

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.
- 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.
- ISO 11135:2014 + Amd1:2018
  Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices.
- 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 29th of May 2019

Sinikka Tiisala
Business Director

Actim Oy - A subsidiary of Medix Biochemica

HEADQUARTERS
Klovippelontie 3
FI-02180 Espoo, Finland

MANUFACTURING SITE
Nojjakantie 13
FI-80130 Joensuu, Finland

medix@medixbiochemica.com
www.medixbiochemica.com
VAT reg. no. FI29540422