



## Declaration of Conformity

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

IVD product **Actim® PROM 1ngeni (Product code 30831RETAC)**  
**Actim® 1ngeni (product code 19100AC)**

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.

**SFS-EN ISO 23640:2015 (ISO 23640:2011)**  
In vitro diagnostic medical devices. Evaluation of stability of *in vitro* diagnostic reagents.

**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 28<sup>th</sup> of June 2019

**Sinikka Tiisala**  
Business Director

**Actim Oy - A subsidiary of Medix Biochemica**

**HEADQUARTERS**  
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