



Declaration of Conformity

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

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

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 14th of May 2020

Sinikka Tiisala
Vice-President
Diagnostic tests Business Unit