



## Declaration of Conformity

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

IVD product **Actim® PROM Test (Product code 30830ETAL, 30831ETAL, 30832ETAL)**

**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: 2019**  
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 15223-1:2021**  
Medical devices — Symbols to be used with information to be supplied by the manufacturer — 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 16<sup>th</sup> of December 2021**



**Magnus Pålsson**  
**Managing Director**