

Declaration of Conformity

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

IVD product **Actim Combi® Hemoglobin Transferrin Controls** (Product code 30310ETAC)

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.

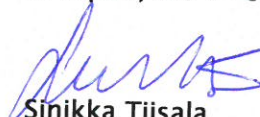
SFS-EN ISO 18113-1:2012
In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements.

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.

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

HEADQUARTERS
 Kloivinpellontie 3
 FI-02180 Espoo, Finland

MANUFACTURING SITE
 Noljakantie 13
 FI-80130 Joensuu, Finland

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