Declaration of Conformity

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

IVD product: Actim® Partus (Product code 31930ETAC and 31931ETAC)

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:
  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.
  In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements.
  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 18th of June 2019

Sinikka Tiisala
Business Director

Actim Oy - A subsidiary of Medix Biochemica

HEADQUARTERS
Klovinpellontie 3
FI-02180 Espoo, Finland

MANUFACTURING SITE
Nojakantie 13
FI-80130 Joensuu, Finland

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