

## Declaration of Conformity

**Manufacturer:**

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**Products: see attachment 1**

**Conformity assessment route: IVDD Annex III**

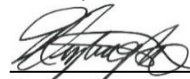
**We, the manufacturer, under the sole responsibility, hereby declare that:**

The product with CE mark manufactured by our company meet the provisions of the EU Council Directive (IVDD 98/79/EC) of In Vitro Diagnostic Medical Devices. The product can fulfill the intended use.

The products includes LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY, BIOCHEMILUMINESCENT ON AUTOMATED INSTRUMENT, Homogeneous Biochemiluminescence Rapid Test (HBA) and INSTRUMENT.

**Date of starting CE-marking: 2018-02-21**

**Place, Date of Issue:** Durham, USA, 2018-02-21



General Manager: Mr. James Li