Declaration of Conformity

Manufacturer:	**Cellex, Inc.** 76 TW Alexander Drive, Research Triangle Park, NC 27709-0002, USA T: 001-301-9057269
European Representative:	**MedPath GmbH** Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany T: +49(0)89 189174474 F: +49(0)89 5485 8884

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

Attachment 1

Products Name	CE Classification	Risk classification	EDMA Code	First CE Marking
LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY				
Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test	Others	Low Risk	15 70 90 90 00	2020-02-01