Declaration of Conformity

CE

Manufacturer:

Cellex, Inc.

Address：

Headquarter:

76 TW Alexander Drive, Research Triangle Park, NC 27709-0002, USA

TEL: 1-919-314-5536 FAX: 1-919-314-5536

Manufacture Location:

1F, North Black, 16 Building, 8 Jinfeng Road, Suzhou New District, Jiangsu, P.R. China, 215011

TEL: +86-512-66897003 FAX: +86-512-66897002

European Representative:

MedPath GmbH

Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Tel: +49-89-189174476 FAX: +49-89-54858884

Email: info@medpath.pro

Product Name:

Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test

（Lateral Flow Chromatographic Immunoassay）

Classification: Others (IVDD, Annex II)

Conformity Assessment Route: IVDD 98/79/EC Annex III

We herewith declare under sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 October 1998 ON IN VITRO DIAGNOSTICS MEDICAL DEVICES

Standard Applied:

EN ISO 13485: 2016 EN 13612:2002EN 13695: 2002EN 980:2016

EN ISO 14971: 2012 EN 13640: 2002 EN 17511: 2003EN 375:2001

Start of CE-MARK: Mar 02, 2020

Place: Headquarter: Research Triangle Park, NC, USA

Manufacture Location: Suzhou, Jiangsu, P.R. China

Date of Issue: Mar 02, 2020

Signature: 

Position: General Manager

Product Name	Cat. No
Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test	5513