

## 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**

| <b>Products Name</b>                            | <b>CE Classification</b> | <b>Risk classification</b> | <b>EDMA Code</b> | <b>First CE Marking</b> |
|---|--------------------------|----------------------------|------------------|-------------------------|
| <b>LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY</b> |                          |                            |                  |                         |
| Cellex qSyphilis Ab Cassette Rapid Test         | Others                   | Low Risk                   | 15 01 03 03 00   | 2018-02-21              |
| Cellex qSyphilis Ab Strip Rapid Test            | Others                   | Low Risk                   | 15 01 03 03 00   | 2018-02-21              |
| Cellex qHAV IgM Cassette Rapid Test             | Others                   | Low Risk                   | 15 02 01 06 00   | 2018-02-21              |
| Cellex qHAV IgM Strip Rapid Test                | Others                   | Low Risk                   | 15 02 01 06 00   | 2018-02-21              |
| Cellex qHEV IgM Cassette Rapid Test             | Others                   | Low Risk                   | 15 02 05 06 00   | 2018-02-21              |
| Cellex qHEV IgM Strip Rapid Test                | Others                   | Low Risk                   | 15 02 05 06 00   | 2018-02-21              |
| Cellex qHSV1 IgG/IgM Cassette Rapid Test        | Others                   | Low Risk                   | 15 04 03 07 00   | 2018-02-21              |
| Cellex qHSV1 IgG/IgM Strip Rapid Test           | Others                   | Low Risk                   | 15 04 03 07 00   | 2018-02-21              |
| Cellex qHSV2 IgG/IgM Cassette Rapid Test        | Others                   | Low Risk                   | 15 04 03 10 00   | 2018-02-21              |
| Cellex qHSV2 IgG/IgM Strip Rapid Test           | Others                   | Low Risk                   | 15 04 03 10 00   | 2018-02-21              |
| Cellex qLeptospira IgG/IgM Cassette Rapid Test  | Others                   | Low Risk                   | 15 01 90 04 00   | 2018-02-21              |
| Cellex qLeptospira IgG/IgM Strip Rapid Test     | Others                   | Low Risk                   | 15 01 90 04 00   | 2018-02-21              |
| Cellex qInfluenza A/B Cassette Rapid Test       | Others                   | Low Risk                   | 15 04 80 04 00   | 2018-02-21              |
| Cellex qInfluenza A/B Strip Rapid Test          | Others                   | Low Risk                   | 15 04 80 04 00   | 2018-02-21              |
| Cellex qTB IgG/IgM Cassette Rapid Test          | Others                   | Low Risk                   | 15 04 80 90 00   | 2018-02-21              |
| Cellex qTB IgG/IgM Strip Rapid Test             | Others                   | Low Risk                   | 15 04 80 90 00   | 2018-02-21              |
| Cellex qDengue IgG/IgM Cassette Rapid Test      | Others                   | Low Risk                   | 15 04 80 11 00   | 2018-02-21              |
| Cellex qDengue IgG/IgM Strip Rapid Test         | Others                   | Low Risk                   | 15 04 80 11 00   | 2018-02-21              |
| Cellex qDengue NS1/IgG/IgM Cassette Rapid Test  | Others                   | Low Risk                   | 15 04 80 11 00   | 2018-02-21              |
| Cellex qDengue NS1/IgG/IgM Strip Rapid Test     | Others                   | Low Risk                   | 15 04 80 11 00   | 2018-02-21              |
| Cellex qDengue NS1 Cassette Rapid Test          | Others                   | Low Risk                   | 15 04 80 11 00   | 2018-02-21              |
| Cellex qDengue NS1 Strip Rapid Test             | Others                   | Low Risk                   | 15 04 80 11 00   | 2018-02-21              |
| Cellex qChikungunya IgM Cassette Rapid Test     | Others                   | Low Risk                   | 15 04 80 90 00   | 2018-02-21              |
| Cellex qChikungunya IgM Strip Rapid Test        | Others                   | Low Risk                   | 15 04 80 90 00   | 2018-02-21              |
| Cellex qChikungunya IgG/IgM Cassette Rapid Test | Others                   | Low Risk                   | 15 04 80 90 00   | 2018-02-21              |
| Cellex qChikungunya IgG/IgM Strip Rapid Test    | Others                   | Low Risk                   | 15 04 80 90 00   | 2018-02-21              |

|  |        |          |                |            |
|--|--------|----------|----------------|------------|
| Cellex qDengue IgG/IgM/Chikungunya IgM Cassette Combo Rapid Test | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qDengue IgG/IgM/Chikungunya IgM Strip Combo Rapid Test    | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qMalaria Pf/Pv Ab Cassette Rapid Test                     | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qMalaria Pf/Pv Ab Strip Rapid Test                        | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qMalaria Pf/Pv Ag Cassette Rapid Test                     | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qMalaria Pf/Pv Ag Strip Rapid Test                        | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qMalaria Pf/Pan Ag Cassette Rapid Test                    | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qMalaria Pf/Pan Ag Strip Rapid Test                       | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qMalaria Pf Ag Cassette Rapid Test                        | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qMalaria Pf Ag Strip Rapid Test                           | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qChagas Ab Cassette Rapid Test                            | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qChagas Ab Strip Rapid Test                               | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qFilariasis IgG/IgM Cassette Rapid Test                   | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qFilariasis IgG/IgM Strip Rapid Test                      | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qTyphoid IgG/IgM Cassette Rapid Test                      | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qTyphoid IgG/IgM Strip Rapid Test                         | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qTyphoid Ag Cassette Rapid Test                           | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qTyphoid Ag Strip Rapid Test                              | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qTyphoid Ag/IgG/IgM Cassette Rapid Test                   | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qTyphoid Ag/IgG/IgM Strip Rapid Test                      | Others | Low Risk | 15 04 80 90 00 | 2018-02-21 |
| Cellex qLeishmania IgG/IgM Cassette Rapid Test                   | Others | Low Risk | 15 05 10 05 00 | 2018-02-21 |
| Cellex qLeishmania IgG/IgM Strip Rapid Test                      | Others | Low Risk | 15 05 10 05 00 | 2018-02-21 |
| Cellex qH. pylori Ab Cassette Rapid Test                         | Others | Low Risk | 15 01 04 03 00 | 2018-02-21 |
| Cellex qH. pylori Ab Strip Rapid Test                            | Others | Low Risk | 15 01 04 03 00 | 2018-02-21 |
| Cellex qH. pylori Ag Cassette Rapid Test                         | Others | Low Risk | 15 01 04 01 00 | 2018-02-21 |
| Cellex qH. pylori Ag Strip Rapid Test                            | Others | Low Risk | 15 01 04 01 00 | 2018-02-21 |

|  |        |          |                |            |
|--|--------|----------|----------------|------------|
| Cellex qFOB Cassette Rapid Test                    | Others | Low Risk | 12 03 90 04 00 | 2018-02-21 |
| Cellex qFOB Strip Rapid Test                       | Others | Low Risk | 12 03 90 04 00 | 2018-02-21 |
| Cellex qRotavirus Ag Cassette Rapid Test           | Others | Low Risk | 15 04 80 06 00 | 2018-02-21 |
| Cellex qRotavirus Ag Strip Rapid Test              | Others | Low Risk | 15 04 80 06 00 | 2018-02-21 |
| Cellex qhCG Cassette Rapid Test                    | Others | Low Risk | 12 70 05 02 00 | 2018-02-21 |
| Cellex qhCG Strip Rapid Test                       | Others | Low Risk | 12 70 05 02 00 | 2018-02-21 |
| Cellex qLH Cassette Rapid Test                     | Others | Low Risk | 12 70 05 04 00 | 2018-02-21 |
| Cellex qLH Strip Rapid Test                        | Others | Low Risk | 12 70 05 04 00 | 2018-02-21 |
| Cellex HbA1c Quantitative Test                     | Others | Low Risk | 11 02 01 14 00 | 2018-02-21 |
| Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test     | Others | Low Risk | 15 70 90 90 00 | 2020-02-01 |
| <b>BIOCHEMILUMINESCENT ON AUTOMATED INSTRUMENT</b> |        |          |                |            |
| Helios CRP Quantitative Test                       | Others | Low Risk | 12 70 11 01 00 | 2018-02-21 |
| Helios PCT Quantitative Test                       | Others | Low Risk | 12 06 90 16 00 | 2018-02-21 |
| Helios CRP/PCT Quantitative Test                   | Others | Low Risk | 12 70 13 90 00 | 2018-02-21 |
| Helios NGAL Quantitative Test                      | Others | Low Risk | 12 90 90 90 00 | 2018-02-21 |
| Helios MAU Quantitative Test                       | Others | Low Risk | 12 70 02 90 00 | 2018-02-21 |
| Helios $\beta$ 2-MG Quantitative Test              | Others | Low Risk | 12 03 90 02 00 | 2018-02-21 |
| Helios H-FABP Quantitative Test                    | Others | Low Risk | 12 13 01 03 00 | 2018-02-21 |
| Helios cTnI Quantitative Test                      | Others | Low Risk | 12 70 13 90 00 | 2018-02-21 |
| Helios MYO Quantitative Test                       | Others | Low Risk | 12 70 13 02 00 | 2018-02-21 |
| Helios CK-MB Quantitative Test                     | Others | Low Risk | 12 70 13 01 00 | 2018-02-21 |
| Helios cTnI/NT-proBNP Quantitative Test            | Others | Low Risk | 12 70 13 90 00 | 2018-02-21 |
| Helios SAA Quantitative Test                       | Others | Low Risk | 12 70 11 90 00 | 2018-02-21 |
| Helios Ferritin Quantitative Test                  | Others | Low Risk | 12 07 01 02 00 | 2018-02-21 |
| Helios HbA1c Quantitative Test                     | Others | Low Risk | 11 70 01 07 00 | 2018-02-21 |
| Helios TT3 Quantitative Test                       | Others | Low Risk | 12 04 01 05 00 | 2018-02-21 |
| Helios TT4 Quantitative Test                       | Others | Low Risk | 12 04 01 07 00 | 2018-02-21 |
| Helios TSH Quantitative Test                       | Others | Low Risk | 12 04 01 11 00 | 2018-02-21 |
| Helios Cys-C Quantitative Test                     | Others | Low Risk | 12 01 90 90 00 | 2018-02-21 |
| Helios $\beta$ -HCG Quantitative Test              | Others | Low Risk | 12 05 02 06 00 | 2018-02-21 |
| Helios CEA Quantitative Test                       | Others | Low Risk | 12 03 01 31 00 | 2018-02-21 |
| Helios D-Dimer Quantitative Test                   | Others | Low Risk | 13 02 70 03 00 | 2018-02-21 |
| Helios NT-proBNP Quantitative Test                 | Others | Low Risk | 12 70 13 90 00 | 2018-02-21 |
| Helios fPSA Quantitative Test                      | Others | Low Risk | 12 03 01 33 00 | 2018-02-21 |
| Helios Vitamin D Quantitative Test                 | Others | Low Risk | 12 07 02 90 00 | 2018-02-21 |
| Helios AFP Quantitative Test                       | Others | Low Risk | 12 03 90 01 00 | 2018-02-21 |
| Helios LH Quantitative Test                        | Others | Low Risk | 12 70 05 01 00 | 2018-02-21 |
| Helios FSH Quantitative Test                       | Others | Low Risk | 12 05 01 04 00 | 2018-02-21 |
| Helios PRL Quantitative Test                       | Others | Low Risk | 12 05 01 08 00 | 2018-02-21 |
| <b>INSTRUMENT</b>                                  |        |          |                |            |
| Helios Luminometer 100                             | Others | Low Risk | 22 03 02       | 2018-02-21 |
| Helios Luminometer 120                             | Others | Low Risk | 22 03 02       | 2018-02-21 |

|  |        |          |                |            |
|--|--------|----------|----------------|------------|
| Helios Analyzer  | Others | Low Risk | 22 03 02       | 2018-02-21 |
| HbA1c Analyzer 303                                       | Others | Low Risk | 22 03 02       | 2018-02-21 |
| <b>Homogeneous Biochemiluminescence Rapid Test (HBA)</b> |        |          |                |            |
| qFlu Dx Rapid Test                                       | Others | Low Risk | 15 70 90 90 00 | 2018-02-21 |
| qFlu Mx Rapid Test                                       | Others | Low Risk | 15 70 90 90 00 | 2018-02-21 |
| qBV Rapid Test   | Others | Low Risk | 15 70 01 90 00 | 2018-02-21 |
| qAR1 Rapid Test  | Others | Low Risk | 12 08 03 90 00 | 2018-02-21 |
| qAR2 Rapid Test  | Others | Low Risk | 12 08 03 90 00 | 2018-02-21 |
| qUTI Rapid Test  | Others | Low Risk | 12 70 11 90 00 |            |
| qHP Rapid Test   | Others | Low Risk | 15 70 01 02 00 |            |