NO. MGIWH-DoC0010014

# Declaration of Conformity

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| **MANUFACTURER:** | Wuhan MGI Tech Co., Ltd.<br>Building 24, Stage 3.1, BioLake Accelerator, No.388, 2nd Gaoxin Road, East Lake High-Tech Development Zone,430075, Wuhan, P.R.China |
| **European Representative:** | Shanghai International Holding Corp. GmbH (Europe)<br>Eiffestrasse 80, 20537 Hamburg, Germany |
| **PRODUCT TYPE:** | Sample Transfer Processing System |
| **MODEL:** | MGISTP-3000 |
| **Classification:** | Device not in IVDD annex II and not for self-testing/performance evaluation. |
| **Conformity Assessment Route:** | IVDD Annex III (excluding Section 6) |
| **CE Mark Affixed:** | 2021 |

We, (Wuhan MGI Tech Co., Ltd.), herewith declare that the above-mentioned product meets the transposition into national law, the provisions of Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. All supporting documentation is retained at the premises of the manufacturer.

The construction of the product in compliance with the following harmonized and/or consensus standards.

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| IEC 61010-1:2010+AMD1:2016<br>EN 61010-1:2010+A1:2019 | Safety requirements for electrical equipment for measurement, control, and laboratory use - Part1-General requirements |
| IEC 61010-2-101:2018<br>EN 61010-2-101:2017 | Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment |
| IEC 61326-1:2012<br>EN 61326-1:2013 | Electrical equipment for measurement, control and laboratory use – EMC requirements Part 1: General requirements |
| IEC 61326-2-6:2012<br>EN 61326-2-6:2013 | Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment |

Authorized by:

张伟

Director, Regulatory Affairs

2021/3/30

Date