



NO. MGIWH-DoC0010011

## Declaration of Conformity

**MANUFACTURER:** Wuhan MGI Tech Co., Ltd.  
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)  
Eiffelstrasse 80, 20537 Hamburg, Germany

**PRODUCT TYPE:** Automated Nucleic Acid Extractor

**MODEL:** MGISP-NE384

**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:** 2020

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.

IEC 61010-1:2010+AMD1:2016 EN 61010-1:2010/A1:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1-General requirements
IEC 61010-2-101:2018	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61010-2-010:2019	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
IEC 61326-1:2012	Electrical equipment for measurement, control and laboratory use – EMC requirements Part 1: General requirements
IEC 61326-2-6:2012	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

2020/9/30

Date