NO. MGIWH-DoC0010004-001

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, China
European Representative:	Shanghai International Holding Corp. GmbH (Europe)
	Eiffestrasse 80, 20537 Hamburg, Germany
PRODUCT TYPE:	High-throughput Automated Sample Preparation System
MODEL:	MGISP-960
Classification:	The 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:	2019

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 EN 61010-1:2010 UL 61010-1:2012 CAN/CSA-C22.2 No. 61010-1-12	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part1-General requirements
IEC 61010-2-101:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61010-2-010:2014	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

3/18/2020

Date