Declaration of Conformity

Manufacturer: Shenzhen Meixiangbio Medical Technology Co., Ltd.

SRN:

Address: 608-609, East block, Building 2, Minqi Science Park, No. 65, Lishan Road, Pingshan community, Taoyuan Street, Nanshan District, Shenzhen, Guangdong, P. R. China

European Authorized Representative: Obelis s.a.

Registered Address: Bd. Général Wahis 53 B-1030 Brussels, Belgium

Product name: Auto Haematology Analyzer

MODEL： MX-5200、MX-5250、MX-5260、MX-5270

Product code： 50001.21061X

Catalogue number： MX2106

Basic UDI-DI: 697597749MX-52003D

INTENED Purpose： Auto Hematology Analyzers is suitable for use in clinical testing as a measurement of blood cell counts, White blood cell five-differential counts , and hemoglobin concentrations.

Classification: Class A, rule 5(b), Annex VIII of IVDR.

Conformity Assessment Procedure:
Declare the conformity of the product by issuing the EU declaration of conformity after drawing up the technical documentation set out in Annexes II and III of IVDR

Our current Quality System is formatted to international standards:

ISO13485:2016 EN 980:2008 EN ISO 14971:2019 EN ISO 15223-1:2016 EN 13612:2002 EN ISO 18113-1:2011 EN 23640:2015 EN ISO 17511:2021 EN 62366-1:2015/A1:2020

We herewith declare that the above-mentioned products meet the regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. All supporting documentation is retained at the premises of the manufacturer.

The manufacturer is sole responsible for the Declaration of Conformity.

Authorized by:

Person responsible for gulatory compliance	Place	Date
Shen Long	SHENZHEN	2023.01.08