DECLARATION OF CONFORMITY

ACCORDING TO In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746

Digitally signed by Jighili Tatiana
Date: 2025.07.21 11:30:21 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands
SRN: NL-AR-000000247

Device Classification

Classification: Class A.

Rule: According to Rule 5, Annex VIII, of In Vitro Diagnostic Medical Devices Regulation (EU)2017/746.

Applicable Standards

EN ISO 20417: 2021
EN ISO 15223-1:2016
EN ISO 18113-1:2011
EN ISO 18113-3:2011
EN ISO 14971:2019

Manufacturer

Name: Hunan Xiang Yi Laboratory Instrument Development Co.,LTD
Address: No.35 Jinsui Road, Wangcheng Economic Development Zone, Changsha City, Hunan Province, 410200, P.R. China

Product Information

Name: CENTRIFUGE
Model:M16,H1650-W,H1650K,H1650,H1750,H1850, TG16-WS,HT190,HT180,CHT210,CHT205,TG16-W, TG12M,HT150R,H1650R,H1750R,HT180R,H2100R, H2500R,H2050R,TGL-20M,H1850R,TGL-16M,TGL-16, HT165R,HT190R,CHT210R CHT205R,TGL-16K, H16R,L530R, L535R, CLT55R, TD3, TD4, TDZ4K, TDZ4-WS, L420-A, L500-A, L600-A, LT53, CLT55, L550, L530, TD5A-WS, TDZ5-WS, L400, L420, L500, L600, L600A, A500, WTL-4K, WTL-6K, WTL-10K, PRP100, PRP200, PRP400, PRP500, L500PRP, TXD3, TD-12K,TD-24K,XKA-2200,MM7,MM8,MM9,MM10,Orbital 360,Orbital 260,Orbital 460,Orbital 160,Cell Cycle 360,VS 3000.
GMDN: 36465

Basic UDI-DI: 697140297XYCEN0205W

Classification: Class A

Conformity Assessment

Compliance of the designated product with the In Vitro Diagnostic Medical Devices Regulation (EU)2017/746 has been assessed by issuing the EU declaration of conformity referred to in Article 17 after drawing up the

technical documentation set out in Annexes II and III.

Remark

The declaration of conformity is valid in connection with the release technical document CE/IVDR-GPTC-02.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Declaration

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 and the applicable standards above.

Signature: Wenjing Zhou Date: 2022.10.27

Position :Marketing Director Place: Changsha/China