DECLARATION OF CONFORMITY

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

EU Representative

SUNGO Cert Gmbh

Harffstr. 47,40591 Düsseldorf, Germany

SRN: DE-AR-000010869

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 14971:2019

Remark

The declaration of conformity is valid in connection with the release technical document CE/IVDR-MC-03.

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.

Manufacturer

Name: Shaoxing Shangyu Mingji Plastic Co.,Ltd.

Address: Shengqiao, Xiaoyue, Shangyu, Shaoxing, Zhejiang, China 312367

Product Information

Name: CRYO TUBE

Model: CT0010I, CT0020I, CT0030I, CT0040I, CT0050I, CT0010E, CT0020E, CT0030E, CT0040E, CT0050E, CRS81, CRA81, CRC81, CRS100, CRA100, CRC100, CRC25

GMDN: 64783

Basic UDI-DI:

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.

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.

Digitally signed by Ionașcu Andrei
Date: 2022.10.28 16:12:09 EEST
Reason: MoldSign Signature
Location: Moldova

Signature: Song yiping Date:2021.8.19

Position: GM Place: Shaoxing/China