Declaration of Conformity

Manufacturer:	**Name and Address** Name:Zhejiang Gongdong Medical Technology Co., Ltd. Registered address: No.10 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China. Production address: (1) No.10 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China. (2) No.88 Jingxian Road, Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China.
SRN of the Manufacturer:	CN-MF-000005694
Authorised Representative:	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg, Germany
SRN of the Authorised Rep.:	DE-AR-000000001
Product Name:	Specimen Container
Basic UDI-DI of Product:	6947462411111169MD
Intended Purpose:	The product is intended to be used to for collection, transportation and storage of samples.
EMDN Code:	W05019099

Classification (IVDR, Annex VIII): **A, rule 5**

Conformity Assessment Procedure: **Pursuant to Regulation(EU)2017/746 on In Vitro Diagnostic Medical Devices, Annex IX Chapters I and III.**

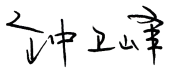
We (manufacturer) herewith state that the above-mentioned product is in conformity with the following In Vitro Diagnostic Regulation, Common Specifications and Product Standards. We are solely responsible for the EU declaration of conformity.

The applicable In Vitro Diagnostic Regulation, Common Specifications and Product Standards: In Vitro Diagnostic Regulation (EU) 2017/746

Reference Standards:

EN ISO 14971: 2019
EN ISO 20417:2021
EN ISO 13485:2016
EN ISO 18113-1: 2011
EN ISO15223-1:2021

Signature:



Name: Zhong Weifeng
Position: General Manager
Place, Date of Issue: Tai Zhou, 2023.08.27