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.39 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China. （3）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:	Urine Transfer Straw
Product Code:	**11.1240.100**
Basic UDI-DI of Product:	6947462411111153LW
Intended Purpose:	Use to transfer small volume of urine from an open container to help prevent direct exposure of clinicians to urine specimens.
EMDN Code:	W05010202

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

Conformity Assessment Procedure: **Pursuant to Regulation(EU)2017/746 on In Vitro Diagnostic Medical Devices, Annex II + 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

Standards:

EN ISO 14971: 2019
EN ISO 10993-1: 2020
EN ISO 10993-10:2013
EN ISO 13485:2016
EN ISO 18113-1: 2011
EN ISO 10993-5: 2009
EN ISO 20417:2021

Signature:

Name:	Shi Huiyong
Position:	President
Place, Date of Issue:	Tai Zhou, 2023.01.06