



DECLARATION OF CONFORMITY

Regarding Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR)

Manufacturer: Jiangsu CoWin Biotech Co., Ltd.

Address: 4F, Building TQB No.1, China Medicine City Avenue, Taizhou, Jiangsu, China

Manufacturer SRN: CN-MF-000008981

EU Representative: CMC Medical Devices & Drugs S.L

Address: C/Horacio Lengo N° 18 CP 29006, Málaga-Spain

EU Representative SRN: ES-AR-000000293

Basic UDI-DI: 697445472V22004X005X0088H

Product Name: Cell-Free DNA Storage Tube

Intended Use: It intended for collection, transport and storage of blood samples.

Classification: Class A of ANNEX VIII of IVDR EU 2017/746

Conformity Assessment Route: Article 48(10)

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) and the following standards. All supporting documentations are retained under the premises of the manufacturer.

ISO 6710-2017	ISO 13485:2016	ISO 15223-1:2021
ISO 18113-2:2009	ISO 18113-1:2009	ISO 14971:2019

Signature:

Name/ Position: Wang Haibing / GM

Date: 2022.07

Place: TAIZHOU/ CHINA

