

EC DECLARATION OF CONFORMITY

According to the In-vitro Diagnostic Devices Directive (98/79/EC)

Manufacturer: Name: Anhui Sinic Laboratory Medicine Technology Co., Ltd.

> Add: No.2, Dongyi North Road, Economic & Technology Zone,231400 Tongcheng, Anhui, PEOPLE'S RUPUBLIC OF

CHINA

Trade name / Trademark: N.A.

SRN: Not available yet

European Representative: Name: MedPath GmbH

Add: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

SRN: DE-AR-000000087

N.A. Trade Name:

Product Model: Vacuum Tube: EDTA-K3 Tube, No additives Tube, SST Tube, Lithium Heparin Tube,

Blood Collection Tube

Gel+Heparin Lithium Tube, PT Tube, ESR Tube, Glucose Tube, EDTA-K2 Tube, Clot Activator Tube, NaF+EDTA-K2 Tube, Sodium fluoride Tube, Sodium Heparin Tube, Gel+Sodium Heparin Tube, Sodium Citrate Tube, Gel+ Sodium Citrate Tube, ACD+Gel

Tube, Gel Tube, Imidazole Alkyl Urea/Glycine/EDTA-K3 Tube

Micro Tube: PT Tube, ESR Tube, Clot Activator Tube, EDTA-K2 Tube, EDTA-K3 Tube, Gel Tube, SST Tube, Gel+Heparin Lithium Tube, Gel+Sodium Heparin Tube, Gel+ Sodium Citrate Tube, Lithium Heparin Tube, NaF+EDTA-K2 Tube, Glucose Tube, No

additives Tube, Sodium fluoride Tube, Sodium Heparin Tube

Basic UDI-DI Not available yet

Product Classification: Others

EDMA Code: 14 01 02 20 00

Conformity assessment IVDD 98/79/EC, Annex III ex. Sec.6

procedure:

Product Name:

DIRECTIVES

General applicable directives:

In Vitro Diagnostic Medical Devices Directive: IVDD 98/79/EC

We here with declare in sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

Date of Issue: 2022.01.16

Tongcheng, Anhui, China

Signature:

Position: General Manager





