Products Certification Body
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

CERTIFICATE

NO.20 0665T/ITC

confirm that the products - in vitro diagnostic medical devices - according to the Directive 98/79/EC:

Blood Collection Tube

Models: **Plain Tube, EDTA-3K Tube, SST Tube, Lithium Heparin Tube, Gel + Heparin Tube (Lithium), PT Tube, ESR Tube, Glucose Tube, Micro Plain Tube, Micro EDTA-3K Tube, Micro Gel Tube, Micro PT Tube, ACD + Gel, Sodium Citrate + Gel**

manufactured by company

Anhui Sinic Laboratory Medicine Technology Co., Ltd.
Sinic Technology Zone, Dongyi North Road, Economic Technology Zone, Tongcheng, Anhui, China

comply with the applicable essential requirements of the European Parliament and of the Council Directive 98/79/EC on in vitro diagnostic medical devices as amended.

Referring to the intended use, the ITC Products Certification Body has conducted with successful results the type-examination of the certified product according to the relevant parts of the above mentioned Directive and appropriate harmonized European standards.

The detailed product descriptions, documents, assessment procedures and evaluations of the examination are presented in the Final Report NO.316600336/2020, which is enclosed to this certificate.

Conditions of this Certificate use and related information:

1. *It applies only to the above referenced models of the medical devices.*
2. *It does not imply that the ITC has performed any surveillance or control of their manufacture.*
3. *The manufacturer is obligated to assure conformity of all in vitro diagnostic medical devices of the respective model to type assessed by the mean of this Certificate.*
4. *The Certificate remains valid until the manufacturing conditions, the quality system or relevant legislation are changed but until the* 31th November2023 *at the latest.*
5. *After fulfilling of the relevant EU legislation requirements, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking according to this example:*

CE

Issued in Zlin, on 5th November2020

Institut pro testování a certifikaci, a.s. Zlín

RNDr. Radomír Ševelík
General Director