Digitally signed by Jighili Tatiana
Date: 2023.09.15 18:52:07 EEST
Reason: MoldSign Signature
Location: Moldova

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:	Anji SPENQ Industrial Co., Ltd. F16,Building C, Anji Chamber of Commerce Mansion, No.99 Tianhuangping South Road, Anji County, Zhejiang Province, PEOPLE’ S REPUBLIC OF CHINA
SRN:	CN-MF-000021677
European Representative:	CMC Medical Devices & Drugs S.L C/Horacio Lengo No 18 CP 29006, Málaga-Spain
SRN:	ES-AR-000000293
Trade name:	vacuum blood collection tube
Product name:	Vacuum blood collection tube,
Specification:	2ml,3ml,4ml,5ml,6ml,7ml,8ml,9ml,10ml,etc
Product code / Catalogue number:	SO1701,SO1702,SO1703
Basic UDI:	697485893SA01T9
Classification acc. to MDR Ax. VIII:	Class IIa
Applied Standard & Common Specification:	EN ISO 10993-1:2020 / EN ISO 10993-5:2009 EN ISO 10993-10:2013/ EN ISO 14971:2019
Conformity assessment procedure:	Annex II + Annex III of Regulation EU 2017/745(MDR)

CE

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Gao Baihong, General Manager

Anji, Zhejiang, 18. 11. 2022