

# 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  
CN-MF-000021677

**SRN:**

**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)



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.

A handwritten signature in black ink, appearing to read '高百红' (Gao Baihong).

Gao Baihong, General Manager

Anji, Zhejiang, 18. 11. 2022