

SRN:



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

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 EN ISO 10993-1:2020 / EN ISO 10993-5:2009

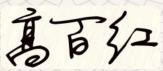
Specification:

EN ISO 10993-10:2013/ EN ISO 14971:2019

Conformity assessment procedure: Annex II + Annex III of Regulation EU 2017/745(MDR)

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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





