淮安市天达医疗器械有限公司
HuaiAn TianDa Medical Instruments Co.,Ltd

Declaration of Conformity

Manufacturer:HUAIAN TIANDA MEDICAL INSTRUMENTS CO.,LTD.
Add: No.106 East Songjiang Road,Huaiyin Economic&Technological Development Zone 223300 Huaian City,Jiangsu China
European Representative:RIOMAVIX SOCIEDAD LIMITADA
Add: Calle de Almansa 55, 1D， Madrid 28039 Spain
SRN: ES-AR-000001202
Product: Sterile Blood Lancets
Model: Twist1、Twist2、Twist3、Twist4、Twist5
Size: 18G,21G,23G,26G,28G,30G,L,S
EMDN Code:V010401 LANCETS WITH SAFETY SYSTEMS, SINGLE-USE
V010402 LANCETS WITHOUT SAFETY SYSTEMS, SINGLE-USE
Basic UDI-DI: Twist:69519338BLFW

Indication of use:
Sterile Blood Lancets used for skin puncture in clinical medicine to collect human peripheral blood samples.

Classification: Class IIa, rule 6
We here with declare that the above mentioned products meet the provisions of Directive 93/42/EEC which apply to them,
The Medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC,It bears the mark CE0197.
The product concerned has been manufactured under a quality management system according to Annex V& Annex VII of Directive 93/42/EEC.

DIRECTIVES

General Applicable Directive:
Medical Device Directive**:**COUNCIL DIRECTIVE MDD 93/42/EEC of 14 June 1993 concerning medical device (MDD 93/42/EEC)、Regulation(EU)2017/745(MDR)

Standards:
All applicable harmonized standard (published in the Official Journal of the European Communities e.g EN ISO 14971:2019，EN ISO20417:2021，EN 556-1:2001，EN ISO 7153-1:2016，ISO10993-1:2018，EN ISO 10993-5:2009，EN ISO 10993-10:2023，ISO10993-11:2017，ISO 10993-23:2021，EN ISO 11137-1:2015，EN ISO 11137-2:2015，EN ISO 11607-1:2020，EN ISO 11607-2:2020，EN ISO 11737-1:2018，EN ISO11737-2:2020，EN 17141:2020，EN ISO 15223-1:2021，DIN EN 62366-1(August 2021).)

Notified Body Confirmation Letter

Reference. : 244592151

Date of issuance: April 19, 2024

NotifyBody: TÜV Rheinland LGA Products GmbH-Tillystraße 2-90431 Nürnberg

MDD/AIMDD Certificate Reference(s) of the devices under MDR application

Certificate: DD601477430001

Date CE Certificate is Expired:2028-12-31

Date CE mark was affixed:2020-10-08

SRN Number:CN-MF-000031504

Place: HuaiAn JiangSu **Date:**2024-05-08

Signature:

Name: Chen Zhiyong
Position: General Manager