EC Declaration of Conformity

Manufacturer: Shandong Chengwu Medical Products Factory
274200 Southern End of Quancheng Road, Chengwu County,
Shandong Province, P.R.China

European Representative: SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam

Product Name: **Disposable sterile venous blood specimen collection needle**

Model: soft-connection; hard-connection

UMDNS Code: 12736

Classification (MDD, Annex IX): **Class IIa, Rule 6**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and All applicable harmonised Standards. All supporting documentations are retained under the premises of the manufacturer.
Shandong Chengwu Medical Products Factory is exclusively responsible for the declaration of conformity

DIRECTIVES

Medical Device Directive:
COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC), Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

Notified Body : TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, MÜnchen, Germany

NB Identification number: 0123

(EC) Certificate(s): G2 103129 0002 Rev. 00

Expire date of the Certificate: 2024-02-22

Start of CE Marking: 2019-12-06

Place, Date of Issue: Shandong Chengwu 2019.12.06

Signature/date: Wang Jicun 2019.12.06

Name: Wang Jicun

Position: General Manager

Vacuum Blood Collection Tube, Gel & Clot Activator Tube

Material: PET, Glass
Color: Yellow

Cat. No.	Specification	Volume	Additive	Qty/case (Glass)	Qty/case (PET)
630201	13×75mm	3ml	Gel & Clot Activator	1800	1800
630202	13×75mm	4ml	Gel & Clot Activator	1800	1800
630203	13×75mm	5ml	Gel & Clot Activator	1800	1800
630204	13X100mm	5ml	Gel & Clot Activator	1200	1200
630205	13×100mm	6ml	Gel & Clot Activator	1200	1200
630206	13×100mm	8ml	Gel & Clot Activator	1200	1200
630207	16x100mm	8ml	Gel & Clot Activator	1200	1200
630208	16×100mm	9ml	Gel & Clot Activator	1200	1200
630209	16×100mm	10ml	Gel & Clot Activator	1200	1200

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q6 003096 0003 Rev. 01

Holder of Certificate:

Guangzhou iCare Medical Technology Co., Ltd.
First floor A No.8
Lianhua Port Industrial Zone
Lotus Mountain Bonded Area, Shilou Town
Panyu District
511440 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate:

Production and Distribution of Insulin pen needles, Safety Lancets, Disposable Insulin Syringes (with Needle), Alcohol Pads

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6 003096 0003 Rev. 01

Report No.: SH21124101

Valid from: 2021-08-27
Valid until: 2024-06-28

Date, 2021-08-27

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q6 003096 0003 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Guangzhou iCare Medical Technology Co., Ltd.
First floor A No.8, Lianhua Port Industrial Zone, Lotus Mountain Bonded Area, Shilou Town, Panyu District, 511440 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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