DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICE

MANUFACTURER:	Hebei Xinle Sci&Tech Co.,Ltd No. 2, Xingye Street, Xinle City, 050700 Shijiazhuang City, Hebei province, PEOPLE'S REPUBLIC OF CHINA
MEDICAL DEVICE:	Venous blood collection needles XLPI-18G, 85.3154, 85.3155 XLPI-20G, 85.3156
CLASSIFICATION-ANNEX IX:	Class IIa Rule 6
CONFORMITY ASSESSMENT ROUTE:	MDD 93/42/EEC Annex V

WE, **HEBEI XINLE SCI&TECH CO., LTD**, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICE MEET THE TRANSPOSITION INTO NATIONAL LOW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERING MEDICAL DEVICE; INCLUDING AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL RIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PRMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH Ridlerstraße 65, 80339 Munich, Germany
IDENTIFICATION NUMBER	CE 0123
(EC) CERTIFICATE（S）	G2 065764 0004 REV.02
EC REP **EUROPEAN PRERESENTATIVE**	Shanghai International Holding Corp. GMBH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany. Tel: 0086-021-65951371, 0049-40-2513175, Fax: 0049-40-255726

START OF CE-MARKING: 12, SEP, 2014

THIS DOCUMENT IS VALID BY: 26, MAY, 2024

PLACE, DATE OF DECLARATION:	XINLE, 29, DEC, 2020
SIGNATURE	NAME: MR. TIAN JIANXUN POSITION: MANAGEMENT REPRESENTATIVE

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 065764 0004 Rev. 02

Manufacturer:

Hebei Xinle Sci&Tech Co.,Ltd
No.2, Xingye Street, Xinle City
050700 Shijiazhuang City, Hebei Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Venous Blood Collection Needles, Lancet.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. 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:G2 065764 0004 Rev. 02

Report No.: BJ20096102

Valid from: 2020-12-15
Valid until: 2024-05-26

Date, 2020-12-15

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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