# CE Technical File

## Declaration of Conformity

Manufacturer: **Jiangsu Kangjian Medical Apparatus Co., Ltd.**
**No. 16 Zhanqian Road, Jiangyan 225500, Taizhou,Jiangsu, China**

European Representative: **Linkfar Healthcare GmbH**
**St.-Franziskus-Str. 112 40470 Dusseldorf Germany**
**Dimid No. DE/0000047135**
**Tel: +49-21192411577**
**Fax:+49-21192411577**
**E-mail: jane@linkfar.de**

Product Name: **Vacuum Blood Collection System**
UMDNS Code: **12748**

Classification (MDD Annex IX): IIa, Rule 6

Conformity Assessment Route: **V.3 + VII.3 of IVD 93/42/EEC**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

## General applicable directives:

Medical Device Directive: COUNCAL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC) amended by 2007/47/EC.

Standard Applied:
EN980:2008 EN1041:2008 EN ISO 13485:2012/AC:2009
EN ISO 14971:2007

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr 65, 80339 Munchen, Germany
NB Identification number: 0123
(EC) Certificate(s): G2 11 06 93445 006

Expire date of the Certificate: **2021-04-10**

Place, Date of Issue: **Jiangsu, 2017-6-10**

Signature: _____

Name: **Ding Jin**

Position: **Managing Director**