KLFmed

EU Declaration of Conformity

According to ANNEX IV of the Medical Device Regulation (EU) 2017/745

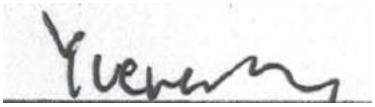
Manufacturer:	**Wenzhou K.L.F. Medical Plastics Co., Ltd No.29 Gangqiang Road, Airport New Area, Yongxing Street, Longwan District, 325000 Wenzhou, Zhejiang, People's Republic of China**
SRN of the Manufacturer:	**CN-MF-000011214**
Authorised Representative:	**Shanghai International Holding Corp. GmbH(Europe) Eiffestraße, 20537 Hamburg, Germany**
SRN of the Authorised Rep.:	**DE-AR-000000001**
Product Name:	**INFUSION SET FOR INFUSION PUMP**
Product Code:	**60000,60006,60012,60214,60913,60014.**
Basic UDI-DI of Product:	**6944262910B0201TB**
Intended Purpose:	**INFUSION SET FOR INFUSION PUMP is intended to be used with an intravenous needle or catheter to conduct fluids from an intravenous fluid container to a patient's venous system during pressure administration.**
EMDN Code:	**A030101- INFUSION CONTROLLERS**

Classification (MDR, Annex VIII): **IIa, rule 2, 1st indent**
Conformity Assessment Procedure: **Annex XI**

We (manufacturer) herewith state that the above-mentioned product is in conformity with the following Medical Device Regulation, Common Specifications and Product Standards. We are solely responsible for the EU declaration of conformity.

The applicable Medical Device Regulation, Common Specifications and Product Standards:

Medical Device Regulation (EU) 2017/745
Common Specifications: N/A
EN ISO 8536-8:2015

Notified Body:	**TÜV SÜD Product Service GmbH Ridlerstr. 65, 80339, München, Germany**
Identification number:	**CE0123**
(EC) Certificate(s):	**G20 047985 0029 Rev.00**
Expire date of the Certificate:	**2027-12-07**
Signature:	
Name:	**Yuewen Jiang**
Position:	**Person responsible for regulatory compliance**
Place, Date of Issue:	**Wenzhou, 2023-02-23**