KLFmed

EU Declaration of Conformity

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

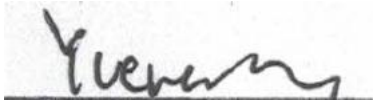
Manufacturer:	**Wenzhou K.L.F. Medical Plastics Co., Ltd No.29 Gangqiang Road, Airport New Area, Yongxing Street, Longwan District, 325000 Wenzhou, Zhejiang, People's Republic of China**
SRN of the Manufacturer:	**CN-MF-000011214**
Authorised Representative:	**Shanghai International Holding Corp. GmbH(Europe) Eiffestraße, 20537 Hamburg, Germany**
SRN of the Authorised Rep.:	**DE-AR-000000001**
Product Name:	**LUER LOCK CAP**
Product Code:	**NDCU10,NDCU11.**
Basic UDI-DI of Product:	**6944262911A0000SZ**
Intended Purpose:	**LUER LOCK CAP IS INTENDED TO PROTECT THE PATH OR STOPPER THE SOLUTION OF INFUSION DEVICE.**
EMDN Code:	**A070501-CAPS OR OBTURATORS, NON-PERFORABLE**

Classification (MDR, Annex VIII): **Is, rule 1, no 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 80369-7:2017

Notified Body:	**TÜV SÜD Product Service GmbH Ridlerstr. 65, 80339, München, Germany**
Identification number:	**CE0123**
(EC) Certificate(s):	**G21 047985 0030 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, 2023-02-03**