

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Name and address of the manufacturer: **Changzhou Shunfeng Plastic Co., Ltd.**
No.129, West Lane Shunbei Village Committee, Zhenglu
Town, Tianning District 213116 Changzhou City, Jiangsu
Province PEOPLE'S REPUBLIC OF CHINA

SRN: CN-MF-000014926

Name and address European Representative: CMC Medical Devices & Drugs S.L.
C/Horacio Lengo N° 18, CP 29006 Málaga, SPAIN

SRN: ES-AR-000000293

Trade name: Sterile Vaginal Speculum for Single Use

Product name: Sterile Vaginal Speculum for Single Use

EMDN code U089006

Product model SF-CK001, SF-CK002, SF-CK003, SF-CK004,
SF-CK005,

Applied standard EN ISO 14971:2019 , EN ISO 10993-1:2020,
EN ISO 10993-5:2009, EN ISO 20993-10:2013

Basic UDI-DI: 697009789SVS001WG

Intended Use: Vaginal expansion and gynecological examination of
clinical use.

Classification acc. to MDR Ax. VIII: Class Is, rule 5

Conformity assessment procedure: Annex XI Part A of the Regulation EU 2017/745(MDR)

CE certificate no.: G21 072517 0011 REV.01

Issue date: 2023-06-13

Valid until: 2028-06-12

Name, address and ID of the Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65 80339 MÜNCHEN, Germany



We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.



 General manager
Name and function

Attached: Model list and REF NO.



Model	REF NO.
SF-CK001	VS0017, VS0018, VS0019, VS0017P, VS0018P, VS0019P, VS0017E, VS0018E, VS0019E,
SF-CK002	VS0027, VS0028, VS0029, VS0027P, VS0028P, VS0029P, VS0027E, VS0028E, VS0029E,
SF-CK003	VS0037, VS0038, VS0039, VS0037P, VS0038P, VS0039P, VS0037E, VS0038E, VS0039E,
SF-CK004	VS0047, VS0048, VS0049, VS0047P, VS0048P, VS0049P, VS0047E, VS0048E, VS0049E,
SF-CK005	VS0055, VS0056, VS0057, VS0058, VS0059, VS0055P, VS0056P, VS0057P, VS0058P, VS0059P, VS0055E, VS0056E, VS0057E, VS0058E, VS0059E,