

	EC Declaration of Conformity — Disposable Plastic Forceps	Document No.:	GD/MDR01-08
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EU Declaration of Conformity

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

Manufacturer:	Name and Address Name: Zhejiang Gongdong Medical Technology Co., Ltd. Registered address: No.10 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China. Production address: (1) No.10 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China. (2) No.39 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China. (3) No.88 Jingxian Road, Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China.
SRN of the Manufacturer:	CN-MF-000005694
Authorised Representative:	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg, Germany
SRN of the Authorised Rep.:	DE-AR-000000001
Product Name:	Disposable Plastic Forceps
Basic UDI-DI of Product:	694746241111110LC
Intended Purpose:	Disposable Plastic Forceps are intended to be used for the hospital's surgical operations for holding dressing.
EMDN Code:	Q030304

Classification (MDR, Annex VIII): **Is, rule 1**

Conformity Assessment Procedure: **Pursuant to Regulation(EU)2017/745 on Medical Devices, Annex IX Chapters I and III.**

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:

EN ISO 14971: 2019
EN ISO 10993-1: 2020
EN ISO 10993-10:2013
EN ISO 13485:2016

EN ISO 15223-1: 2021
EN ISO 10993-5: 2009
EN ISO 20417:2021
EN ISO 11135:2014

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Notified Body: TÜV SÜD Product Service GmbH
Ridlerstr. 65, 80339, München, Germany
Identification number: CE0123
(EC) Certificate(s): **G11 042464 0038 Rev. 00**
Expire date of the Certificate: **2028-08-09**
Signature: 
Name: Zhong Weifeng
Position: General Manager
Place, Date of Issue: Tai Zhou, 2023.08.10

