

CE Technical File Examination Gloves with Paper	File No: HY-CE-2.4-01
	Rev. No: 00

EU Declaration of Conformity

Manufacturer: Zhangjiagang Hengya Plastic Products Co., Ltd.
Address: South Side of Shanzheng Road, Shanzheng Village, Jingang Town, 215631
Zhangjiagang City PEOPLE' S REPUBLIC OF CHINA

Authorised Representative: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg Germany

Product Name: Examination Gloves with Paper

SRN: CN-MF- 000028789

Model and Type: HYD(HYD-L, HYD-M, HYD-S), HYS (HYS-L, HYS-M, HYS-S)

Basic UDI-DI: 6973422920211GD01SC

Product Code: HYD(HYD-L, HYD-M, HYD-S), HYS (HYS-L, HYS-M, HYS-S)

Classification (MDR, Rule 5 of Annex VIII CHAPTER III): I sterile

Conformity assessment procedure: ANNEX XI Part A

We herewith declare that the above mentioned products meet the provisions of the following regulation and harmonized standards published on the Official Journal of the European Union, and that this EU declaration of conformity is issued under the sole responsibility of Zhangjiagang Hengya Plastic Products Co., Ltd.

Regulation

General applicable regulations:

Medical Device Regulation: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Notified Body: TUV SUD Product Service GmbH, Ridlerstraße 65, 80339 Munchen, Germany

NB Identification number: 0123

Certificate: G21 062384 0015 Rev.00

Expiration date of the certificate: 2028-09-24

Place, Date: Zhangjiagang Hengya Plastic Products Co., Ltd. South Side of Shanzheng Road, Shanzheng Village, Jingang Town, 215631 Zhangjiagang City PEOPLE' S REPUBLIC OF CHINA

Signature

 2024.3.12

Name: Ji Jianzhong

Position: General Manager

