

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

EU Declaration of Conformity

1. MANUFACTURER INFORMATION

- Name: Zhangjiagang Hengya Plastic Products Co., Ltd.
- Address: South Side of Shanzheng Road, Shanzheng Village, Jingang Town, 215631
Zhangjiagang City, PEOPLE'S REPUBLIC OF CHINA
- Contact Person: Ji Jianzhong
- E-mail / Tel: jjzhy@zjghengya.com
- Single Registration Number (SRN): CN-MF- 000028789

2. EUROPEAN AUTHORIZED REPRESENTATIVE (if applicable)

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

3. PRODUCT IDENTIFICATION

- Product Name: Examination Gloves with Paper
- Brand/Model: HYD(HYD-L, HYD-M, HYD-S)
- Basic UDI-DI: 6973422920211GD01SC
- Description: Sterile.Single-use.The gloves are made of polyethylene film and laminated to medical packaging paper.They possess sufficient strength and barrier properties.Providing barrier protection to prevent cross-contamination.
- Intended Use (detailed): For protective purposes, it is worn on the hands or fingers of medical personnel during examination or palpation to prevent cross-contamination between the user and the patient, and to protect the user from exposure to potentially harmful substances.
- Precautions: Not for use by persons with hypersensitivity to plastic materials.
- Device Classification: I sterile (MDR, Rule 5 of Annex VIII CHAPTER III)

4. LEGAL BASIS & CONFORMITY

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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.

5. HARMONIZED STANDARDS APPLIED

- (EU) 2017/745 on medical devices, Annex XI Part A

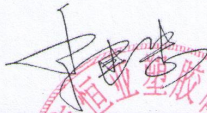
6. NOTIFIED BODY (if applicable – for Class IIa/IIb/III)

- Name: TUV SUD Product Service GmbH, Ridlerstraße 65, 80339 München, Germany
- Identification Number: 0123
- Certificate Number: G21 062384 0015 Rev. 00
- Expiration date of the certificate: 2028-09-24

8. ADDITIONAL DECLARATIONS

9. ISSUE DETAILS

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

Signature: 

Name: Ji Jianzhong

Position: General Manager

Date: 2026.6.2

