

Zhangjiagang Hengya Plastic Products Co., Ltd. CE Technical Files	File No: HY/CE-Part A	Version: B/0
	Subject: Declaration of Conformity	Page 1, Total page 1

Manufacturer: Zhangjiagang Hengya Plastic Products Co., Ltd.

Address: South Side of shanzheng Road,Shanzheng Village, Jingang Town, 215631, Zhangjiagang City
PEOPLES REPUBLIC OF CHINA

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Hamburg)

Address: Eiffestrasse 80, 20537, Hamburg GERMANY

PRODUCTS: Examination Gloves with Paper

Examination Gloves With Paper (11882) SIZE: Single(L/M/S)/Double(L/M/S)

UMDNS code: 11882

Classification (MDD, Annex IX): I sterile, rule 5

Conformity Assessment Route: Annex V.3

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. The manufacturer is exclusively responsible for the declaration of conformity.

DIRECTIVES

Medical Device Directive: COUNCIL DIRECTIVE DIRECTIVE 93/42/EEC concerning medical devices.

Standard Applied: See attached list of (Harmonized – EN) standards for which documented evidence of compliance can be provided.

Notified Body: TÜV SÜD Product Service GmbH

Address: Ridlerstr. 65, 80339 München, Germany

Identification number: CE 0123

(EC) Certificate(s): G2S 062384 0014 Rev.00, Examination Gloves with Paper

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2007-6-26

Place, Date of Issue: Zhangjiagang

Signature:

The stamp is circular and red, containing the company name in Chinese characters: 张家港市恒亚塑胶制品有限公司. In the center is a red star. A handwritten signature in black ink is written across the stamp. Below the star, the number '822186169' is visible.

Name: General manage

Position: Zhangjiagang