



CARATTERISTICHE GENERALI

Guanto sterile in copolimero/sterile gloves with paper
privo di lattice.

Supporto guanto in carta.

Involucro: carta/film per sterilizzazione

Sterilizzazione: Raggi gamma -validità sterilizzazione 5 anni

Colore: trasparente.

Rev.2017



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 062384 0014 Rev. 00

Manufacturer

**Zhangjiagang Hengya
Plastic Products Co., Ltd.**

South Side of Shanzheng Road
Shanzheng Village, Jingang Town
215631 Zhangjiagang City
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

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

Product Category(ies):

**Examination Gloves with Paper,
PE Long Examination Gloves**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH19136EXT01

Valid from: 2020-02-26

Valid until: 2024-05-26

Date, 2020-02-26

Christoph Dicks
Head of Certification/Notified Body

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:



Name: General manage

Position: Zhangjiagang