



Certificate CN15/21464

The management system of

Zhenjiang Huayang Latex Products Co., Ltd.

Lianhe Village, Xinba Town,
Yangzhong City, Jiangsu Province, 212212, P.R. China

has been assessed and certified as meeting the requirements of



ISO 13485:2016 EN ISO 13485:2016

For the following activities

**Manufacture of Sterile Latex Surgical Gloves, Sterile Latex
Examination Gloves and Non-Sterile Latex, Nitrile and PVC
Examination Gloves**

This certificate is valid from 19 October 2018 until 18 October 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 16 July 2021
Issue 2. Certified since 19 October 2015

Authorised by

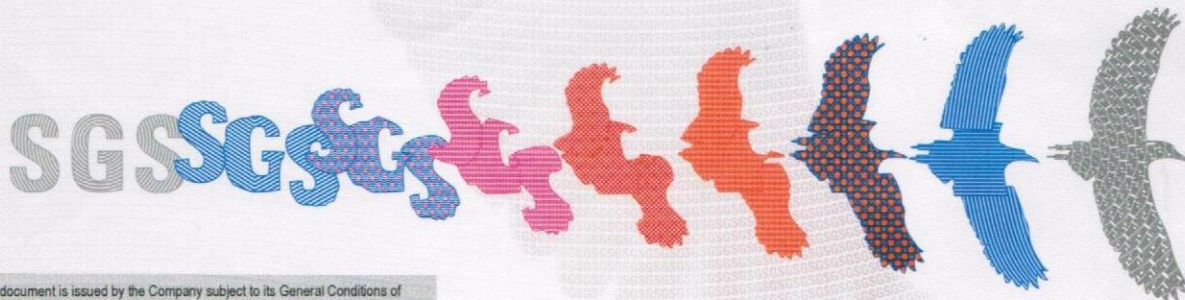
SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire CH65 3EN, UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

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EC Declaration of Conformity

Manufacturer:

Zhenjiang Huayang Latex Products Co., Ltd
Lianhe Village Xinba Town Yangzhong City
Jiangsu Province, P.R.China

EC-representative:

Name: MedPath GmbH
DIMDI No.: DE/0000047823
Add: Mies-van-der-Rohe Strasse 8, 80807
Munich, Germany
Tel: +49(0)89 189174474 Fax: +49(0)89
5485 8884
E-mail: info@medpath.pro
Sales Tax ID: DE313841775
Responsible Competent Authority: BfArM,
Germany
Code of the Authority: DE/CA61

Product name: Nitrile Examination Gloves
Classification (MDD, Annex IX): class I, rule 1.

Conformity Assessment Route: Annex VII

We, the manufacturer, herewith declare that the products

Nitrile Examination Gloves

UMDNS-Code: 11882

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC.

It bears the mark



The product concerned has been manufactured under a quality management system according to Annex VII of Directive 93/42/EEC.

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company:

Zhenjiang Huayang Latex Products Co., Ltd
Lianhe Village Xinba Town Yangzhong City Jiangsu Province, P.R.China

WangXueBin 2020.02.05

Place, date



Legally binding signature, Function