



## Compliance Report

**Applicant:** Zhangjiagang Wenhao Industrial Co., Ltd.  
**Address:** No.8 Chuangye Road, Fenghuang Town, Zhangjiagang City, Jiangsu Province, China 215614

**Product:** PE Glove, PE Apron, CPE Gown (Isolation Gown)  
**Type:** See annex for details

**Product Classification:** Class II

**The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).**

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

**No. 02491**  
**Initial Issue Date: 23 Mar 2016**

*Tony Chen*

General Manager (Signature)



**Annex to Report (No. 02491 )**

**Zhangjiagang Wenhao Industrial Co., Ltd.**

Product Name	Type
PE Glove	S,M,L,XL
PE Apron	69*107cm,69*122cm,71*117cm,80*125cm,80*140cm; According to customers' special requirements
CPE Gown (Isolation Gown)	S,M,L,XL

This annex is only valid if attached to the report mentioned above.

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