



Compliance Report

Applicant: Jiangsu Dingjie Medical Equipment Co., Ltd.
Address: No. 219 Yanjiang Road, Changjiang Town, Rugao City,
Nantong City, Jiangsu Province, China

Product: Disposable Vinyl Examination Gloves
Type: See annex for details

Product Classification: Class I

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. 03055

Initial Issue Date: 2 Apr 2019

Tony Chen

General Manager (Signature)

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Annex to Report (No. 03055)

Jiangsu Dingjie Medical Equipment Co., Ltd.

Product Name	Type
Disposable Vinyl Examination Gloves	9 inch, Powder free, Clear Color
	9 inch, Powdered, Clear Color
	9 inch, Powder free, Blue Color
	9 inch, Powdered, Blue Color
	9 inch, Powder free, Yellow Color
	9 inch, Powdered, Yellow Color

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

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