



**EU Declaration of Conformity**  
**according to (EU) 2017/745 and (EU) 2016/425**

We,

Anhui Intco Medical Products Co., Ltd.  
No.6, Haitang South Road, Suixi Wuhu Modern Industrial Park, Suixi County,  
Huaibei City, Anhui Province, P.R. China

Single registration number (SRN): CN-MF-000002356

**Authorized Representative: Lotus NL B.V., Koinigin Julianaplein 10, le Verd  
2595AA, The Hague, Netherlands**

Single registration number (SRN): NL-AR-000000121

Hereby declare under their sole responsibility of the following product group:

- Disposable Vinyl Exam Gloves

**EMDN code: T01020201**

**Basic UDI-DI: 697306977VinylDU**

REF SAP	DESIGNATION
3145827	GANTS VINYLE NON POUURES XS MEDIBASE (100)
3145828	GANTS VINYLE NON POUURES S MEDIBASE (100)
3145829	GANTS VINYLE NON POUURES M MEDIBASE (100)
3145830	GANTS VINYLE NON POUURES L MEDIBASE (100)
3145831	GANTS VINYLE NON POUURES XL MEDIBASE (100)

Complies with the conformity assessment procedure set out in Annex IV of Regulation (EU) 2017/745 and all applicable essential safety and performance requirements of Annex I are met. And the procedures according to the specifications in Annex II and Annex III of the same regulation have been followed.

The products according to Annex I are risk class I products according to rule 1 and 5 Annex VII (EU) 2017/745.

We assure that the products comply with the provisions of the applicable European legislations, in particular the harmonized standards, national standards or other normative documents listed here:

EN ISO 13485:2016; EN ISO 14971:2019; EN ISO 20417:2021; EN 15223-1:2021; EN 455-1:2020+A2:2024; EN 455-2:2024;  
EN 455-3:2023; EN 455-4:2009; ISO 10993-1:2018; ISO 10993-05:2009; ISO 10993-10:2021; ISO 10993-23:2021.

We also declare under our sole responsibility that the products mentioned in Annex 1 comply with the requirements according to the PPE Regulation 2016/425 and are in conformity with the conformity assessment procedure according to the Regulation 2016/425 and the applicable harmonized standards.

This product is category III PPE according to Annex I of the Regulation. This is identical to the PPE that was the subject of the EU Type Examination Certificate No: 2777/14715-04/E00-00 issued by Satra (identification number 2777) and was subject to the procedure under Module D of Regulation (EU) 2016/425 under the control of the notified body Satra (identification number 2777).

**Document Number:**  
INTCO-CE-DC-PVC Declaration of Conformity for Disposable Vinyl  
Gloves-MDR&PPE

**Version**  
A/3



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We assure that the products comply with the provisions of the applicable European legislations, in particular the harmonized standards, national standards or other normative documents listed here:

EN ISO 21420:2020; EN ISO 374-1:2016+A1: 2018; EN ISO 374-4:2019; EN ISO 374-5:2016

Diese Erklärung ist gültig für ab dem Ausstellungsdatum in Verkehr gebrachter Produkte.  
This declaration is valid for products placed on the market as of the date of issue.

Anhui, 2025-09 -22

Wang Yazhou Quality Manager

*Legally binding signature, Function*

