



Document Number : INTCOAH-CE-DC-PVC-001

Version: A/1

## EU DECLARATION OF CONFORMITY

Manufacturer

**Name: Anhui Intco Medical Products  
Co.,Ltd.**

**Address: No. 6, Haitang South Road, Suixi  
Wuhu Modern Industrial Park, Suixi  
County, Huaibei City, Anhui Province**

Authorized Representative

**Name: Lotus NL B.V.**

**Address: Koningin Julianaplein 10,le Verd,  
2595AA, The Hague, Netherlands**

Declares that the MDR described hereafter

*Product name and model:*

**Disposable Vinyl Exam Gloves**

**EMDN code: T01020201**

**Model: XS/S/M/L/XL/XXL**

**Product Code:** See the following annex I

**Basic UDI-DI:** 697306977VinylDU

**SRN:** CN-MF-000002356

This declaration of conformity is issued under the sole responsibility of the manufacturer:

**Anhui Intco Medical Products Co.,Ltd.**

Conformity Assessment Route: Annex II and Annex III according to EU 2017/745.

Applicable Standard:

EN ISO 13485:2016; EN 14971:2019; EN 1041:2008; EN 15223-1:2016

EN 455-1:2000; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009;

ISO 10993-1:2018; ISO 10993-10:2010. ISO 10993-05:2009.

Meet the provisions of the Council Regulation EU 2017/745 and Annex I which apply to them,

The medical device has been assigned to Class I, based on rule 1 & rule 5 of Annex VIII

Chapter III of the Regulation EU 2017/745 MDR. It bears the mark



We agree to develop, implement and maintain a documented post-production monitoring process



**Annex 1 product code**

Color	Product Code
Clear	VGVBHPEM10003-VGV/B/H/PEM10007
	VGVBHPEM15003-VGV/B/H/PEM15007
	SVVBHPE10003-SVV/B/H/PE10007
	SVVBHPE15003-SVV/B/H/PE15007
Blue	VGVBHPEM10013-VGV/B/H/PEM10017
	VGVBHPEM15013-VGV/B/H/PEM15017
	SVVBHPE10013-SVV/B/H/PE10017
	SVVBHPE15013-SVV/B/H/PE15017
White	VGVBHPEM10023-VGV/B/H/PEM10027
	VGVBHPEM15023-VGV/B/H/PEM15027
	SVVBHPE10023-SVV/B/H/PE10027
	SVVBHPE15023-SVV/B/H/PE15027
Yellow	VGVBHPEM10063-VGV/B/H/PEM10067
	VGVBHPEM15063-VGV/B/H/PEM15067
	SVVBHPE10063-SVV/B/H/PE10067
	SVVBHPE15063-SVV/B/H/PE15067



Anhui 2021-04-16  
Place , date

符志强 Quality Manager  
Legally binding signature, Function  
品质部专用章





安徽英科医疗用品有限公司  
Anhui Intco Medical Products Co., Ltd.

文件编号 Doc No.  
版 本 Ver.

INTCO-PPE-PVC  
AO

### EU Declaration of Conformity

1. PPE: Disposable Vinyl Gloves

Glove sizes available: XS, S, M, L, XL (6, 7, 8, 9,10)

2. Manufacturer Name: Anhui Intco Medical Products Co., Ltd.

Address: No.1 Haitang Road,Suixi District economic development area,HuaiBei City,Anhui Province.

3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Anhui Intco Medical Products Co., Ltd.

4. Object of the declaration: Disposable Vinyl Gloves (Clear-VGPF; Yellow-SMPF; Blue-BMPF; White-WMPF)



5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: EN420:2003+A1:2009, EN ISO 374-1:2016 +A1:2018, EN374-4:2014, EN ISO 374-5:2016;

6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

7. The notified body SATRA Technology Europe Ltd (Number: 2777) performed the EU type-examination (Module B) and issued the EU type-examination certificate.

8. The PPE is subject to the conformity assessment procedure Module C2 under surveillance of the notified body : SATRA Technology (Number: 2777),

Address: Bracetown Business Park Clonee, D15 YN2P, Ireland.

Signed for and on behalf of: Anhui Intco Medical Products Co., Ltd.

签名 Signature 崔忠强

职位 Position Quality Manager

日期 Date 5-May-2020

