



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

Version: A/2

## EU DECLARATION OF CONFORMITY

Manufacturer

Authorized Representative

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

*Name:* Lotus NL B.V.

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

*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:** 697306977VinylIDU

**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 455-1:2020; 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	VGVB/H/PEM10003-VGV/B/H/PEM10007
	VGVB/H/PEM15003-VGV/B/H/PEM15007
	SVVB/H/PE10003-SVV/B/H/PE10007
	SVVB/H/PE15003-SVV/B/H/PE15007
Blue	VGVB/H/PEM10013-VGV/B/H/PEM10017
	VGVB/H/PEM15013-VGV/B/H/PEM15017
	SVVB/H/PE10013-SVV/B/H/PE10017
	SVVB/H/PE15013-SVV/B/H/PE15017
White	VGVB/H/PEM10023-VGV/B/H/PEM10027
	VGVB/H/PEM15023-VGV/B/H/PEM15027
	SVVB/H/PE10023-SVV/B/H/PE10027
	SVVB/H/PE15023-SVV/B/H/PE15027
Yellow	VGVB/H/PEM10063-VGV/B/H/PEM10067
	VGVB/H/PEM15063-VGV/B/H/PEM15067
	SVVB/H/PE10063-SVV/B/H/PE10067
	SVVB/H/PE15063-SVV/B/H/PE15067

Anhui 2021-10-30

Place, date


  
 Quality Manager
   
 Legally binding signature, Function


  
 品有限公司