



Document Number : INTCO-CE-DC-PVC-002

Version: A/0

## EU DECLARATION OF CONFORMITY

Manufacturer

*Name:* Shandong Intco Medical Products Co., Ltd.  
*Address:* Qiwang Road NO.9888, Naoshan Industrial Park, Qingzhou, Shandong, China

Authorized Representative

*Name:* Lotus NL B.V.  
*Address:* Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

Declares that the MDR described hereafter

*Product name and model:*

**Disposable Vinyl Exam Gloves / SYNGUARD® Vinyl Exam Gloves**

**EMDN code: T01020201**

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

**Product Code:** VGV/B/H/PEM, SVV/B/H/PE (Please refer to the attachment for more details).

**Basic UDI-DI:** 697024575Vinyl85

This Declaration of Conformity is issued under the sole responsibility of the manufacturer:

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

**SRN:** CN-MF-000002100

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 10993-5:2009.

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.

Shandong 2021-07-22

Place, date

Rick Cheng, Quality Manager

Legally binding signature function





Attached: Product code

color	Size				
	XS	S	M	L	XL
Clear	VGVBHPEM10003	VGVBHPEM10004	VGVBHPEM10005	VGVBHPEM10006	VGVBHPEM10007
	VGVBHPEM15003	VGVBHPEM15004	VGVBHPEM15005	VGVBHPEM15006	VGVBHPEM15007
	SVVBHPE10003	SVVBHPE10004	SVVBHPE10005	SVVBHPE10006	SVVBHPE10007
	SVVBHPE15003	SVVBHPE15004	SVVBHPE15005	SVVBHPE15006	SVVBHPE15007
Blue	VGVBHPEM10013	VGVBHPEM10014	VGVBHPEM10015	VGVBHPEM10016	VGVBHPEM10017
	VGVBHPEM15013	VGVBHPEM15014	VGVBHPEM15015	VGVBHPEM15016	VGVBHPEM15017
	SVVBHPE10013	SVVBHPE10014	SVVBHPE10015	SVVBHPE10016	SVVBHPE10017
	SVVBHPE15013	SVVBHPE15014	SVVBHPE15015	SVVBHPE15016	SVVBHPE15017
White	VGVBHPEM10023	VGVBHPEM10024	VGVBHPEM10025	VGVBHPEM10026	VGVBHPEM10027
	VGVBHPEM15023	VGVBHPEM15024	VGVBHPEM15025	VGVBHPEM15026	VGVBHPEM15027
	SVVBHPE10023	SVVBHPE10024	SVVBHPE10025	SVVBHPE10026	SVVBHPE10027
	SVVBHPE15023	SVVBHPE15024	SVVBHPE15025	SVVBHPE15026	SVVBHPE15027
Yellow	VGVBHPEM10063	VGVBHPEM10064	VGVBHPEM10065	VGVBHPEM10066	VGVBHPEM10067
	VGVBHPEM15063	VGVBHPEM15064	VGVBHPEM15065	VGVBHPEM15066	VGVBHPEM15067
	SVVBHPE10063	SVVBHPE10064	SVVBHPE10065	SVVBHPE10066	SVVBHPE10067
	SVVBHPE15063	SVVBHPE15064	SVVBHPE15065	SVVBHPE15066	SVVBHPE15067