



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

Version: A/0

## EU DECLARATION OF CONFORMITY

Manufacturer

Authorized Representative

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

*Name:* Lotus NL B.V.

*Address:* Qiwang Road NO.9888, Naoshan Industrial Park, Qingzhou, Shandong, China

*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/XXL

**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	VGVB/H/PEM10003	VGVB/H/PEM10004	VGVB/H/PEM10005	VGVB/H/PEM10006	VGVB/H/PEM10007
	VGVB/H/PEM15003	VGVB/H/PEM15004	VGVB/H/PEM15005	VGVB/H/PEM15006	VGVB/H/PEM15007
	SVVB/H/PE10003	SVVB/H/PE10004	SVVB/H/PE10005	SVVB/H/PE10006	SVVB/H/PE10007
	SVVB/H/PE15003	SVVB/H/PE15004	SVVB/H/PE15005	SVVB/H/PE15006	SVVB/H/PE15007
Blue	VGVB/H/PEM10013	VGVB/H/PEM10014	VGVB/H/PEM10015	VGVB/H/PEM10016	VGVB/H/PEM10017
	VGVB/H/PEM15013	VGVB/H/PEM15014	VGVB/H/PEM15015	VGVB/H/PEM15016	VGVB/H/PEM15017
	SVVB/H/PE10013	SVVB/H/PE10014	SVVB/H/PE10015	SVVB/H/PE10016	SVVB/H/PE10017
	SVVB/H/PE15013	SVVB/H/PE15014	SVVB/H/PE15015	SVVB/H/PE15016	SVVB/H/PE15017
White	VGVB/H/PEM10023	VGVB/H/PEM10024	VGVB/H/PEM10025	VGVB/H/PEM10026	VGVB/H/PEM10027
	VGVB/H/PEM15023	VGVB/H/PEM15024	VGVB/H/PEM15025	VGVB/H/PEM15026	VGVB/H/PEM15027
	SVVB/H/PE10023	SVVB/H/PE10024	SVVB/H/PE10025	SVVB/H/PE10026	SVVB/H/PE10027
	SVVB/H/PE15023	SVVB/H/PE15024	SVVB/H/PE15025	SVVB/H/PE15026	SVVB/H/PE15027
Yellow	VGVB/H/PEM10063	VGVB/H/PEM10064	VGVB/H/PEM10065	VGVB/H/PEM10066	VGVB/H/PEM10067
	VGVB/H/PEM15063	VGVB/H/PEM15064	VGVB/H/PEM15065	VGVB/H/PEM15066	VGVB/H/PEM15067
	SVVB/H/PE10063	SVVB/H/PE10064	SVVB/H/PE10065	SVVB/H/PE10066	SVVB/H/PE10067
	SVVB/H/PE15063	SVVB/H/PE15064	SVVB/H/PE15065	SVVB/H/PE15066	SVVB/H/PE15067