



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

Version: A/2

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/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 ISO 14971:2019; EN ISO 20417:2021; EN ISO 15223-1:2021;

EN 455-1:2020+A2:2024; EN 455-2:2024; EN 455-3:2023; EN 455-4:2009;

EN ISO 10993-1:2020; EN ISO 10993-5:2009; EN ISO 10993-10:2023; EN ISO10993-23:2021.

Intended use: The product is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

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 2024-12-20

Place , date

Liu Yijun 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
	VGVBHPEM10L03	VGVBHPEM10L04	VGVBHPEM10L05	VGVBHPEM10L06	VGVBHPEM10L07
	VGVBHPEM15L03	VGVBHPEM15L04	VGVBHPEM15L05	VGVBHPEM15L06	VGVBHPEM15L07
	SVVBHPE10L03	SVVBHPE10L04	SVVBHPE10L05	SVVBHPE10L06	SVVBHPE10L07
	SVVBHPE15L03	SVVBHPE15L04	SVVBHPE15L05	SVVBHPE15L06	SVVBHPE15L07
Blue	VGVBHPEM10013	VGVBHPEM10014	VGVBHPEM10015	VGVBHPEM10016	VGVBHPEM10017
	VGVBHPEM15013	VGVBHPEM15014	VGVBHPEM15015	VGVBHPEM15016	VGVBHPEM15017
	SVVBHPE10013	SVVBHPE10014	SVVBHPE10015	SVVBHPE10016	SVVBHPE10017
	SVVBHPE15013	SVVBHPE15014	SVVBHPE15015	SVVBHPE15016	SVVBHPE15017
	VGVBHPEM10L13	VGVBHPEM10L14	VGVBHPEM10L15	VGVBHPEM10L16	VGVBHPEM10L17
	VGVBHPEM15L13	VGVBHPEM15L14	VGVBHPEM15L15	VGVBHPEM15L16	VGVBHPEM15L17
	SVVBHPE10L13	SVVBHPE10L14	SVVBHPE10L15	SVVBHPE10L16	SVVBHPE10L17
	SVVBHPE15L13	SVVBHPE15L14	SVVBHPE15L15	SVVBHPE15L16	SVVBHPE15L17



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
	VGVB/H/PEM10L23	VGVB/H/PEM10L24	VGVB/H/PEM10L25	VGVB/H/PEM10L26	VGVB/H/PEM10L27
	VGVB/H/PEM15L23	VGVB/H/PEM15L24	VGVB/H/PEM15L25	VGVB/H/PEM15L26	VGVB/H/PEM15L27
	SVVB/H/PE10L23	SVVB/H/PE10L24	SVVB/H/PE10L25	SVVB/H/PE10L26	SVVB/H/PE10L27
	SVVB/H/PE15L23	SVVB/H/PE15L24	SVVB/H/PE15L25	SVVB/H/PE15L26	SVVB/H/PE15L27
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
	VGVB/H/PEM10L63	VGVB/H/PEM10L64	VGVB/H/PEM10L65	VGVB/H/PEM10L66	VGVB/H/PEM10L67
	VGVB/H/PEM15L63	VGVB/H/PEM15L64	VGVB/H/PEM15L65	VGVB/H/PEM15L66	VGVB/H/PEM15L67
	SVVB/H/PE10L63	SVVB/H/PE10L64	SVVB/H/PE10L65	SVVB/H/PE10L66	SVVB/H/PE10L67
	SVVB/H/PE15L63	SVVB/H/PE15L64	SVVB/H/PE15L65	SVVB/H/PE15L66	SVVB/H/PE15L67