



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

Version: A/1

EU DECLARATION OF CONFORMITY

Manufacturer

Authorized Representative

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

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 Nitrile Exam Gloves / SYNGUARD® Nitrile Exam Gloves

EMDN code: T01020204

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

Product Code: NGV/B/H/PEM; SNV/B/H/PE (Please refer to the attachment for more details.).

Basic UDI-DI: 697024575Nitrile7G

SRN: CN-MF-000002100

This Declaration of Conformity is issued under the sole responsibility of the manufacturer: Shandong 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; ISO 20417:2021; EN 15223-1:2021;
EN 455-1-2020+A1:2022; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009;
ISO 10993-1:2018; ISO 10993-10:2010. ISO 10993-11:2017.

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 2023-11-11
Place, date

Liu Yijun Quality Manager
Legally binding signature, Function

品质部专用章



Attached: Product code

color	Size					
	XS	S	M	L	XL	XXL
Blue	NGV/B/H/PEM10013	NGV/B/H/PEM10014	NGV/B/H/PEM10015	NGV/B/H/PEM10016	NGV/B/H/PEM10017	NGV/B/H/PEM10018
	NGV/B/H/PEM20013	NGV/B/H/PEM20014	NGV/B/H/PEM20015	NGV/B/H/PEM20016	NGV/B/H/PEM20017	NGV/B/H/PEM20018
	SNV/B/H/PE10013	SNV/B/H/PE10014	SNV/B/H/PE10015	SNV/B/H/PE10016	SNV/B/H/PE10017	SNV/B/H/PE10018
	SNV/B/H/PE20013	SNV/B/H/PE20014	SNV/B/H/PE20015	SNV/B/H/PE20016	SNV/B/H/PE20017	SNV/B/H/PE20018
	NGV/B/H/PEM10L13	NGV/B/H/PEM10L14	NGV/B/H/PEM10L15	NGV/B/H/PEM10L16	NGV/B/H/PEM10L17	NGV/B/H/PEM10L18
	NGV/B/H/PEM20L13	NGV/B/H/PEM20L14	NGV/B/H/PEM20L15	NGV/B/H/PEM20L16	NGV/B/H/PEM20L17	NGV/B/H/PEM20L18
	SNV/B/H/PE10L13	SNV/B/H/PE10L14	SNV/B/H/PE10L15	SNV/B/H/PE10L16	SNV/B/H/PE10L17	SNV/B/H/PE10L18
	SNV/B/H/PE20L13	SNV/B/H/PE20L14	SNV/B/H/PE20L15	SNV/B/H/PE20L16	SNV/B/H/PE20L17	SNV/B/H/PE20L18
White	NGV/B/H/PEM10023	NGV/B/H/PEM10024	NGV/B/H/PEM10025	NGV/B/H/PEM10026	NGV/B/H/PEM10027	NGV/B/H/PEM10028
	NGV/B/H/PEM20023	NGV/B/H/PEM20024	NGV/B/H/PEM20025	NGV/B/H/PEM20026	NGV/B/H/PEM20027	NGV/B/H/PEM20028
	SNV/B/H/PE10023	SNV/B/H/PE10024	SNV/B/H/PE10025	SNV/B/H/PE10026	SNV/B/H/PE10027	SNV/B/H/PE10028
	SNV/B/H/PE20023	SNV/B/H/PE20024	SNV/B/H/PE20025	SNV/B/H/PE20026	SNV/B/H/PE20027	SNV/B/H/PE20028
	NGV/B/H/PEM10L23	NGV/B/H/PEM10L24	NGV/B/H/PEM10L25	NGV/B/H/PEM10L26	NGV/B/H/PEM10L27	NGV/B/H/PEM10L28
	NGV/B/H/PEM20L23	NGV/B/H/PEM20L24	NGV/B/H/PEM20L25	NGV/B/H/PEM20L26	NGV/B/H/PEM20L27	NGV/B/H/PEM20L28
	SNV/B/H/PE10L23	SNV/B/H/PE10L24	SNV/B/H/PE10L25	SNV/B/H/PE10L26	SNV/B/H/PE10L27	SNV/B/H/PE10L28
	SNV/B/H/PE20L23	SNV/B/H/PE20L24	SNV/B/H/PE20L25	SNV/B/H/PE20L26	SNV/B/H/PE20L27	SNV/B/H/PE20L28



violet	NGV/B/H/PEM10033	NGV/B/H/PEM10034	NGV/B/H/PEM10035	NGV/B/H/PEM10036	NGV/B/H/PEM10037	NGV/B/H/PEM10038
	NGV/B/H/PEM20033	NGV/B/H/PEM20034	NGV/B/H/PEM20035	NGV/B/H/PEM20036	NGV/B/H/PEM20037	NGV/B/H/PEM20038
	SNV/B/H/PE10033	SNV/B/H/PE10034	SNV/B/H/PE10035	SNV/B/H/PE10036	SNV/B/H/PE10037	SNV/B/H/PE10038
	SNV/B/H/PE20033	SNV/B/H/PE20034	SNV/B/H/PE20035	SNV/B/H/PE20036	SNV/B/H/PE20037	SNV/B/H/PE20038
	NGV/B/H/PEM10L33	NGV/B/H/PEM10L34	NGV/B/H/PEM10L35	NGV/B/H/PEM10L36	NGV/B/H/PEM10L37	NGV/B/H/PEM10L38
	NGV/B/H/PEM20L33	NGV/B/H/PEM20L34	NGV/B/H/PEM20L35	NGV/B/H/PEM20L36	NGV/B/H/PEM20L37	NGV/B/H/PEM20L38
	SNV/B/H/PE10L33	SNV/B/H/PE10L34	SNV/B/H/PE10L35	SNV/B/H/PE10L36	SNV/B/H/PE10L37	SNV/B/H/PE10L38
	SNV/B/H/PE20L33	SNV/B/H/PE20L34	SNV/B/H/PE20L35	SNV/B/H/PE20L36	SNV/B/H/PE20L37	SNV/B/H/PE20L38
Black	NGV/B/H/PEM10043	NGV/B/H/PEM10044	NGV/B/H/PEM10045	NGV/B/H/PEM10046	NGV/B/H/PEM10047	NGV/B/H/PEM10048
	NGV/B/H/PEM20043	NGV/B/H/PEM20044	NGV/B/H/PEM20045	NGV/B/H/PEM20046	NGV/B/H/PEM20047	NGV/B/H/PEM20048
	SNV/B/H/PE10043	SNV/B/H/PE10044	SNV/B/H/PE10045	SNV/B/H/PE10046	SNV/B/H/PE10047	SNV/B/H/PE10048
	SNV/B/H/PE20043	SNV/B/H/PE20044	SNV/B/H/PE20045	SNV/B/H/PE20046	SNV/B/H/PE20047	SNV/B/H/PE20048
	NGV/B/H/PEM10L43	NGV/B/H/PEM10L44	NGV/B/H/PEM10L45	NGV/B/H/PEM10L46	NGV/B/H/PEM10L47	NGV/B/H/PEM10L48
	NGV/B/H/PEM20L43	NGV/B/H/PEM20L44	NGV/B/H/PEM20L45	NGV/B/H/PEM20L46	NGV/B/H/PEM20L47	NGV/B/H/PEM20L48
	SNV/B/H/PE10L43	SNV/B/H/PE10L44	SNV/B/H/PE10L45	SNV/B/H/PE10L46	SNV/B/H/PE10L47	SNV/B/H/PE10L48
	SNV/B/H/PE20L43	SNV/B/H/PE20L44	SNV/B/H/PE20L45	SNV/B/H/PE20L46	SNV/B/H/PE20L47	SNV/B/H/PE20L48



Pink	NGV/B/H/PEM10053	NGV/B/H/PEM10054	NGV/B/H/PEM10055	NGV/B/H/PEM10056	NGV/B/H/PEM10057	NGV/B/H/PEM10058
	NGV/B/H/PEM20053	NGV/B/H/PEM20054	NGV/B/H/PEM20055	NGV/B/H/PEM20056	NGV/B/H/PEM20057	NGV/B/H/PEM20058
	SNV/B/H/PE10053	SNV/B/H/PE10054	SNV/B/H/PE10055	SNV/B/H/PE10056	SNV/B/H/PE10057	SNV/B/H/PE10058
	SNV/B/H/PE20053	SNV/B/H/PE20054	SNV/B/H/PE20055	SNV/B/H/PE20056	SNV/B/H/PE20057	SNV/B/H/PE20058
	NGV/B/H/PEM10L53	NGV/B/H/PEM10L54	NGV/B/H/PEM10L55	NGV/B/H/PEM10L56	NGV/B/H/PEM10L57	NGV/B/H/PEM10L58
	NGV/B/H/PEM20L53	NGV/B/H/PEM20L54	NGV/B/H/PEM20L55	NGV/B/H/PEM20L56	NGV/B/H/PEM20L57	NGV/B/H/PEM20L58
	SNV/B/H/PE10L53	SNV/B/H/PE10L54	SNV/B/H/PE10L55	SNV/B/H/PE10L56	SNV/B/H/PE10L57	SNV/B/H/PE10L58
	SNV/B/H/PE20L53	SNV/B/H/PE20L54	SNV/B/H/PE20L55	SNV/B/H/PE20L56	SNV/B/H/PE20L57	SNV/B/H/PE20L58
Yellow	NGV/B/H/PEM10063	NGV/B/H/PEM10064	NGV/B/H/PEM10065	NGV/B/H/PEM10066	NGV/B/H/PEM10067	NGV/B/H/PEM10068
	NGV/B/H/PEM20063	NGV/B/H/PEM20064	NGV/B/H/PEM20065	NGV/B/H/PEM20066	NGV/B/H/PEM20067	NGV/B/H/PEM20068
	SNV/B/H/PE10063	SNV/B/H/PE10064	SNV/B/H/PE10065	SNV/B/H/PE10066	SNV/B/H/PE10067	SNV/B/H/PE10068
	SNV/B/H/PE20063	SNV/B/H/PE20064	SNV/B/H/PE20065	SNV/B/H/PE20066	SNV/B/H/PE20067	SNV/B/H/PE20068
	NGV/B/H/PEM10L63	NGV/B/H/PEM10L64	NGV/B/H/PEM10L65	NGV/B/H/PEM10L66	NGV/B/H/PEM10L67	NGV/B/H/PEM10L68
	NGV/B/H/PEM20L63	NGV/B/H/PEM20L64	NGV/B/H/PEM20L65	NGV/B/H/PEM20L66	NGV/B/H/PEM20L67	NGV/B/H/PEM20L68
	SNV/B/H/PE10L63	SNV/B/H/PE10L64	SNV/B/H/PE10L65	SNV/B/H/PE10L66	SNV/B/H/PE10L67	SNV/B/H/PE10L68
	SNV/B/H/PE20L63	SNV/B/H/PE20L64	SNV/B/H/PE20L65	SNV/B/H/PE20L66	SNV/B/H/PE20L67	SNV/B/H/PE20L68



Red	NGV/B/H/PEM10073	NGV/B/H/PEM10074	NGV/B/H/PEM10075	NGV/B/H/PEM10076	NGV/B/H/PEM10077	NGV/B/H/PEM10078
	NGV/B/H/PEM20073	NGV/B/H/PEM20074	NGV/B/H/PEM20075	NGV/B/H/PEM20076	NGV/B/H/PEM20077	NGV/B/H/PEM20078
	SNV/B/H/PE10073	SNV/B/H/PE10074	SNV/B/H/PE10075	SNV/B/H/PE10076	SNV/B/H/PE10077	SNV/B/H/PE10078
	SNV/B/H/PE20073	SNV/B/H/PE20074	SNV/B/H/PE20075	SNV/B/H/PE20076	SNV/B/H/PE20077	SNV/B/H/PE20078
	NGV/B/H/PEM10L73	NGV/B/H/PEM10L74	NGV/B/H/PEM10L75	NGV/B/H/PEM10L76	NGV/B/H/PEM10L77	NGV/B/H/PEM10L78
	NGV/B/H/PEM20L73	NGV/B/H/PEM20L74	NGV/B/H/PEM20L75	NGV/B/H/PEM20L76	NGV/B/H/PEM20L77	NGV/B/H/PEM20L78
	SNV/B/H/PE10L73	SNV/B/H/PE10L74	SNV/B/H/PE10L75	SNV/B/H/PE10L76	SNV/B/H/PE10L77	SNV/B/H/PE10L78
	SNV/B/H/PE20L73	SNV/B/H/PE20L74	SNV/B/H/PE20L75	SNV/B/H/PE20L76	SNV/B/H/PE20L77	SNV/B/H/PE20L78
Green	NGV/B/H/PEM10083	NGV/B/H/PEM10084	NGV/B/H/PEM10085	NGV/B/H/PEM10086	NGV/B/H/PEM10087	NGV/B/H/PEM10088
	NGV/B/H/PEM20083	NGV/B/H/PEM20084	NGV/B/H/PEM20085	NGV/B/H/PEM20086	NGV/B/H/PEM20087	NGV/B/H/PEM20088
	SNV/B/H/PE10083	SNV/B/H/PE10084	SNV/B/H/PE10085	SNV/B/H/PE10086	SNV/B/H/PE10087	SNV/B/H/PE10088
	SNV/B/H/PE20083	SNV/B/H/PE20084	SNV/B/H/PE20085	SNV/B/H/PE20086	SNV/B/H/PE20087	SNV/B/H/PE20088
	NGV/B/H/PEM10L83	NGV/B/H/PEM10L84	NGV/B/H/PEM10L85	NGV/B/H/PEM10L86	NGV/B/H/PEM10L87	NGV/B/H/PEM10L88
	NGV/B/H/PEM20L83	NGV/B/H/PEM20L84	NGV/B/H/PEM20L85	NGV/B/H/PEM20L86	NGV/B/H/PEM20L87	NGV/B/H/PEM20L88
	SNV/B/H/PE10L83	SNV/B/H/PE10L84	SNV/B/H/PE10L85	SNV/B/H/PE10L86	SNV/B/H/PE10L87	SNV/B/H/PE10L88
	SNV/B/H/PE20L83	SNV/B/H/PE20L84	SNV/B/H/PE20L85	SNV/B/H/PE20L86	SNV/B/H/PE20L87	SNV/B/H/PE20L88



Orange	NGV/B/H/PEM10093	NGV/B/H/PEM10094	NGV/B/H/PEM10095	NGV/B/H/PEM10096	NGV/B/H/PEM10097	NGV/B/H/PEM10098
	NGV/B/H/PEM20093	NGV/B/H/PEM20094	NGV/B/H/PEM20095	NGV/B/H/PEM20096	NGV/B/H/PEM20097	NGV/B/H/PEM20098
	SNV/B/H/PE10093	SNV/B/H/PE10094	SNV/B/H/PE10095	SNV/B/H/PE10096	SNV/B/H/PE10097	SNV/B/H/PE10098
	SNV/B/H/PE20093	SNV/B/H/PE20094	SNV/B/H/PE20095	SNV/B/H/PE20096	SNV/B/H/PE20097	SNV/B/H/PE20098
	NGV/B/H/PEM10L93	NGV/B/H/PEM10L94	NGV/B/H/PEM10L95	NGV/B/H/PEM10L96	NGV/B/H/PEM10L97	NGV/B/H/PEM10L98
	NGV/B/H/PEM20L93	NGV/B/H/PEM20L94	NGV/B/H/PEM20L95	NGV/B/H/PEM20L96	NGV/B/H/PEM20L97	NGV/B/H/PEM20L98
	SNV/B/H/PE10L93	SNV/B/H/PE10L94	SNV/B/H/PE10L95	SNV/B/H/PE10L96	SNV/B/H/PE10L97	SNV/B/H/PE10L98
	SNV/B/H/PE20L93	SNV/B/H/PE20L94	SNV/B/H/PE20L95	SNV/B/H/PE20L96	SNV/B/H/PE20L97	SNV/B/H/PE20L98