



Document Number : INTCO-CE-DC-NBR-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 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 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 ISO 10993-11:2018; 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 Yinjun 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