



Document Number : INTCO-CE-DC-NBR-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 Nitrile Exam Gloves / SYNGUARD® Nitrile Exam Gloves

EMDN code: T01020204

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

Product Code: NGV/B/H/PEM (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; 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 10993-11:2017.

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 2021-07-22

Place, date

Rick Cheng Quality Manager

Legally binding signature, Function





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
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
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
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