



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

Version: A/0

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:

Synmax Vinyl Exam Gloves / SYNGUARD® SYNMAX VINYL® Exam Gloves

EMDN code: T01020299

Model: XS /S /M /L /XL

Product Code: SGV/B/H/PEM, SSV/B/H/PE (Please refer to the attachment for more details).

Basic UDI-DI: 697024575SynmaxPM

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 10993-5:2009.

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	XXL
Blue	SGV/B/H/PEM10013	SGV/B/H/PEM10014	SGV/B/H/PEM10015	SGV/B/H/PEM10016	SGV/B/H/PEM10017	SGV/B/H/PEM10018
	SGV/B/H/PEM15013	SGV/B/H/PEM15014	SGV/B/H/PEM15015	SGV/B/H/PEM15016	SGV/B/H/PEM15017	SGV/B/H/PEM15018
	SSV/B/H/PE10013	SSV/B/H/PE10014	SSV/B/H/PE10015	SSV/B/H/PE10016	SSV/B/H/PE10017	SSV/B/H/PE10018
	SSV/B/H/PE15013	SSV/B/H/PE15014	SSV/B/H/PE15015	SSV/B/H/PE15016	SSV/B/H/PE15017	SSV/B/H/PE15018
White	SGV/B/H/PEM10023	SGV/B/H/PEM10024	SGV/B/H/PEM10025	SGV/B/H/PEM10026	SGV/B/H/PEM10027	SGV/B/H/PEM10028
	SGV/B/H/PEM15023	SGV/B/H/PEM15024	SGV/B/H/PEM15025	SGV/B/H/PEM15026	SGV/B/H/PEM15027	SGV/B/H/PEM15028
	SSV/B/H/PE10023	SSV/B/H/PE10024	SSV/B/H/PE10025	SSV/B/H/PE10026	SSV/B/H/PE10027	SSV/B/H/PE10028
	SSV/B/H/PE15023	SSV/B/H/PE15024	SSV/B/H/PE15025	SSV/B/H/PE15026	SSV/B/H/PE15027	SSV/B/H/PE15028
violet	SGV/B/H/PEM10033	SGV/B/H/PEM10034	SGV/B/H/PEM10035	SGV/B/H/PEM10036	SGV/B/H/PEM10037	SGV/B/H/PEM10038
	SGV/B/H/PEM15033	SGV/B/H/PEM15034	SGV/B/H/PEM15035	SGV/B/H/PEM15036	SGV/B/H/PEM15037	SGV/B/H/PEM15038
	SSV/B/H/PE10033	SSV/B/H/PE10034	SSV/B/H/PE10035	SSV/B/H/PE10036	SSV/B/H/PE10037	SSV/B/H/PE10038
	SSV/B/H/PE15033	SSV/B/H/PE15034	SSV/B/H/PE15035	SSV/B/H/PE15036	SSV/B/H/PE15037	SSV/B/H/PE15038
Black	SGV/B/H/PEM10043	SGV/B/H/PEM10044	SGV/B/H/PEM10045	SGV/B/H/PEM10046	SGV/B/H/PEM10047	SGV/B/H/PEM10048
	SGV/B/H/PEM15043	SGV/B/H/PEM15044	SGV/B/H/PEM15045	SGV/B/H/PEM15046	SGV/B/H/PEM15047	SGV/B/H/PEM15048
	SSV/B/H/PE10043	SSV/B/H/PE10044	SSV/B/H/PE10045	SSV/B/H/PE10046	SSV/B/H/PE10047	SSV/B/H/PE10048
	SSV/B/H/PE15043	SSV/B/H/PE15044	SSV/B/H/PE15045	SSV/B/H/PE15046	SSV/B/H/PE15047	SSV/B/H/PE15048