



Document Number : INTCO-CE-DC-SNBR-001

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:

SYNGUARD® Nitrile Exam Gloves

EMDN code: T01020204

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

Product Code: 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.

Classification: Class I for medical device(rule 1 & rule 5, Annex VIII MDR), Cat III for PPE

We declare that the production of medical devices as specified above is carried out in accordance with MDR EU 2017/745 and PPE regulation EU 2016/425

MDR Harmonized 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.

PPE Harmonized Standard: EN ISO 21420:2020, EN ISO 374-1:2016 +A1:2018, EN374-4:2014, EN ISO 374-5:2016

The notified body SATRA Technology Europe Ltd (Number: 2777) performed:

- EU type-examination Certificate (Module B), certificate number: 2777/17447-02/E00-00
- Module C2 certificate

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 / Product code					
	XS	S	M	L	XL	XXL
Blue	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	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	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	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