



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

Version: A/0

EU DECLARATION OF CONFORMITY

Manufacturer

Name: Anhui Intco Medical Products
Co.,Ltd.

Address: No. 6, Haitang South Road, Suixi
Wuhu Modern Industrial Park, Suixi
County, Huaibei City, Anhui Province

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: 697306977NitrileFR **SRN:** CN-MF-000002356

This Declaration of Conformity is issued under the sole responsibility of the manufacturer:

Anhui Intco Medical Products Co., Ltd.

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

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+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.

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: 2777/14815-03/E00-00
- Module D certificate

We agree to develop, implement and maintain a documented post-production monitoring
process.

Place , date Anhui 2023-07-20

Legally binding signature, Function Quality Manager



Attached: Product code

Color	Size / Product code					
	XS	S	M	L	XL	XXL
Blue	SNV/B/H/PE10013 21.305.024	SNV/B/H/PE10014 21.305.025	SNV/B/H/PE10015 21.305.026	SNV/B/H/PE10016 21.305.027	SNV/B/H/PE10017 21.305.028	SNV/B/H/PE10018 21.305.029
	SNV/B/H/PE20013 21.315.072	SNV/B/H/PE20014 21.315.073	SNV/B/H/PE20015 21.315.074	SNV/B/H/PE20016 21.315.075	SNV/B/H/PE20017 21.315.076	SNV/B/H/PE20018 21.315.077
White	SNV/B/H/PE10023 21.311.059	SNV/B/H/PE10024 21.311.060	SNV/B/H/PE10025 21.311.061	SNV/B/H/PE10026 21.311.062	SNV/B/H/PE10027 21.311.063	SNV/B/H/PE10028
	SNV/B/H/PE20023 21.311.065	SNV/B/H/PE20024 21.311.066	SNV/B/H/PE20025 21.311.067	SNV/B/H/PE20026 21.311.068	SNV/B/H/PE20027 21.311.069	SNV/B/H/PE20028
violet	SNV/B/H/PE10033 21.306.000	SNV/B/H/PE10034 21.306.001	SNV/B/H/PE10035 21.306.002	SNV/B/H/PE10036 21.306.003	SNV/B/H/PE10037 21.306.004	SNV/B/H/PE10038
	SNV/B/H/PE20033 21.306.006	SNV/B/H/PE20034 21.306.007	SNV/B/H/PE20035 21.306.008	SNV/B/H/PE20036 21.306.009	SNV/B/H/PE20037 21.306.0010	SNV/B/H/PE20038
Black	SNV/B/H/PE10043 21.310.049	SNV/B/H/PE10044 21.310.050	SNV/B/H/PE10045 21.310.051	SNV/B/H/PE10046 21.310.052	SNV/B/H/PE10047 21.310.053	SNV/B/H/PE10048 21.310.054
	SNV/B/H/PE20043 21.310.055	SNV/B/H/PE20044 21.310.056	SNV/B/H/PE20045 21.310.057	SNV/B/H/PE20046 21.310.058	SNV/B/H/PE20047 21.310.059	SNV/B/H/PE20048 21.310.060

