



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

Version: A/1

## 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; ISO 20417:2021;  
EN 15223-1:2021; EN 455-1:2020+A1:2022; EN 455-2:2015; EN 455-3:2015; EN 455-  
4:2009; ISO 10993-1:2018; ISO 10993-10:2021. 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 2023-11-14

Legally binding signature, Function Quality Manager



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