



Document Number : INTCOAH-CE-DC-SPVC-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® Vinyl Exam Gloves**

**EMDN code: T01020201**

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

**Product Code:** SVV/B/H/PE (Please refer to the attachment for more details).

**Basic UDI-DI:** 697306977VinylDU **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

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; N 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 10993-5:2009.

**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: 2777/14715-03/E00-00
- Module D certificate

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

Anhui 2023-11-14

*Place, date*

Quality Manager 

*Legally binding signature, Function*



Attached: Product code

color	Size / Product code						
	XS	S	M	L	XL	XXL	
Clear	SVV/B/H/PE10003	SVV/B/H/PE10004	SVV/B/H/PE10005	SVV/B/H/PE10006	SVV/B/H/PE10007	SVV/B/H/PE10008	
	SVV/B/H/PE15003	SVV/B/H/PE15004	SVV/B/H/PE15005	SVV/B/H/PE15006	SVV/B/H/PE15007	SVV/B/H/PE15008	
Blue	SVV/B/H/PE10013	SVV/B/H/PE10014	SVV/B/H/PE10015	SVV/B/H/PE10016	SVV/B/H/PE10017	SVV/B/H/PE10018	
	SVV/B/H/PE15013	SVV/B/H/PE15014	SVV/B/H/PE15015	SVV/B/H/PE15016	SVV/B/H/PE15017	SVV/B/H/PE15018	
White	SVV/B/H/PE10023	SVV/B/H/PE10024	SVV/B/H/PE10025	SVV/B/H/PE10026	SVV/B/H/PE10027	SVV/B/H/PE10028	
	SVV/B/H/PE15023	SVV/B/H/PE15024	SVV/B/H/PE15025	SVV/B/H/PE15026	SVV/B/H/PE15027	SVV/B/H/PE15028	
Yellow	SVV/B/H/PE10063	SVV/B/H/PE10064	SVV/B/H/PE10065	SVV/B/H/PE10066	SVV/B/H/PE10067	SVV/B/H/PE10068	
	SVV/B/H/PE15063	SVV/B/H/PE15064	SVV/B/H/PE15065	SVV/B/H/PE15066	SVV/B/H/PE15067	SVV/B/H/PE15068	