



Document Number : INTCOAH-CE-DC-SSV-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® SYNMAX VINYL® Exam Gloves**

**EMDN code: T01020299**

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

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

**Basic UDI-DI:** 697306977SynmaxWW **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; EN 15223-1:2021; EN 455-1-2020+A1:2022; EN 455-2:2015; EN 455-3:2015; EN 455-4:1509; ISO 10993-1:2018; ISO 10993-10:2021. ISO 10993-5:1509.

**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: 2777/15276-01/E00-00
- Module C2 certificate

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

Anhui 2023-11-14

Place, date

王书明

Quality Manager

Legally binding signature, Function



Attached: Product code

<b>color</b>	<b>Size / Product code</b>						<b>XXL</b>
	<b>XS</b>	<b>S</b>	<b>M</b>	<b>L</b>	<b>XL</b>		
<b>Blue</b>	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	
<b>White</b>	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	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	
<b>Black</b>	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	