

## EU Declaration of Conformity

according to (EU) 2017/745 und der (EU) 2016/425

We,

**Anhui Inteo Medical Products Co., Ltd.**  
**No.6, Haitang South Road, Suixi Wuhu Modern Industrial Park, Suixi County, Huaibei**  
**City, Anhui Province, P.R. China**

Single registration number (SRN): CN-MF-000002356

**Authorized Representative:** **Lotus NL B.V., Konigin Julianaplein 10, le Verd,**  
**2595AA, The Hague, Netherlands**

Single registration number (SRN): **NL-AR-000000121**

hereby declare under their sole responsibility that the products listed in Annex 1 of the following product group:

- Disposable Nitrile Exam Gloves

*Complies with the conformity assessment procedure set out in Annex IV of Regulation (EU) 2017/745 and all applicable essential safety and performance requirements of Annex I are met. And the procedures according to the specifications in Annex II and Annex III of the same regulation have been followed.*

*The products according to Annex I are risk class I products according to rule 1 and 5 Annex VIII (EU) 2017/745.*

*We assure that the products comply with the provisions of the applicable European legislations, in particular the harmonized standards, national standards or other normative documents listed here:*

- EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, EN ISO 15223-1:2021, 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

*We also declare under our sole responsibility that the products mentioned in Annex 1 comply with the requirements according to the PPE Regulation 2016/425 and are in conformity with the conformity assessment procedure according to the Regulation 2016/425 and the applicable harmonized standards.*

*This product is category III PPE according to Annex I of the Regulation. This is identical to the PPE that was the subject of the EU Type Examination Certificate No: 2777/14815-03/E00-00 issued by Satra (identification number 2777) and was subject to the procedure under Module D (quality assurance of the production process) of Regulation (EU) 2016/425 under the control of the notified body Satra (identification number 2777)..*

*We assure that the products comply with the provisions of the applicable European legislations, in particular the harmonized standards, national standards or other normative documents listed here:*

- EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018, EN 374-4:2019; EN ISO 374-5:2016

*This declaration is valid for products placed on the market as of the date of issue.*

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Anhui, 2022-10 -25

Signature: *Andy Wang* Function (Position) : Quality Manager



## Anlage 1 /Annex 1:

**Produktgruppe/ product group:** Disposable Nitrile Exam Gloves  
**Basis-UDI-DI:** 697306977NitrileFR  
**EMDN code** T01020204

Color	Product Code
Blue	NGV/B/H/PEM10013-NGV/B/H/PEM10018
	NGV/B/H/PEM20013-NGV/B/H/PEM20018
	SNV/B/H/PE10013-SNV/B/H/PE10018
	SNV/B/H/PE20013-SNV/B/H/PE20018
	Hynex 7263506 - 7263511
White	NGV/B/H/PEM10023-NGV/B/H/PEM10028
	NGV/B/H/PEM20023-NGV/B/H/PEM20028
	SNV/B/H/PE10023-SNV/B/H/PE10028
	SNV/B/H/PE20023-SNV/B/H/PE20028
	Hynex 5823506 - 5823511
Purple	NGV/B/H/PEM10033-NGV/B/H/PEM10038
	NGV/B/H/PEM20033-NGV/B/H/PEM20038
	SNV/B/H/PE10033-SNV/B/H/PE10038
	SNV/B/H/PE20033-SNV/B/H/PE20038
Black	NGV/B/H/PEM10043-NGV/B/H/PEM10048
	NGV/B/H/PEM20043-NGV/B/H/PEM20048
	SNV/B/H/PE10043-SNV/B/H/PE10048
	SNV/B/H/PE20043-SNV/B/H/PE20048

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	Hynex 8403506 - 8403511
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