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Version: A/1

## EU DECLARATION OF CONFORMITY

Manufacturer

Authorized Representative

**Name: Anhui Intco Medical Products  
Co.,Ltd.**

**Name: Lotus NL B.V.**

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

**Address: Koningin Julianaplein 10, le Verd,  
2595AA, The Hague, Netherlands**

Declares that the MDR described hereafter

*Product name and model:*

**Accelerator Free Disposable Nitrile Gloves**

**EMDN code: T01020204**

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

**Product Code:** See the following annex I

**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.**

Conformity Assessment Route: Annex II and Annex III according to EU 2017/745.

Applicable 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

Meet the provisions of the Council Regulation EU 2017/745 and Annex I which apply to them,

The medical device has been assigned to Class I, based on rule 1 & rule 5 of Annex VIII

Chapter III of the Regulation EU 2017/745 MDR. It bears the mark



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

**Annex 1 product code**

Color	Product Code
Blue	AFBE10013-AFBE10018
	AFBE20013-AFBE20018
White	AFBE10023-AFBE10028
	AFBE20023-AFBE20028
Voilet	AFBE10033-AFBE10038
	AFBE20033-AFBE20038
Black	AFBE10043-AFBE10048
	AFBE20043-AFBE20048

Anhui 2023-11-20

Place , date



Quality Manager

Legally binding signature. Function

