



Document Number : INTCO-PPE-NBR

Version: A/1

EU DECLARATION OF CONFORMITY

1) This declaration of conformity is issued under the sole responsibility of the manufacturer:

Company Name:		Anhui Intco Medical Products Co., Ltd.				
Address:		No. 6, Haitang South Road, Suixi Wuhu Modern Industrial Park, Suixi County, Huaibei City, Anhui Province				
Intco references						
Colour	XS	S	M	L	XL	XXL
Blue	NGVEM10013	NGVEM10014	NGVEM10015	NGVEM10016	NGVEM10017	NGVEM10018
Blue	NGBEM10013	NGBEM10014	NGBEM10015	NGBEM10016	NGBEM10017	NGBEM10018
Black	NGBEM10043	NGBEM10044	NGBEM10045	NGBEM10046	NGBEM10047	NGBEM10048
Blue	NGHEM10013	NGHEM10014	NGHEM10015	NGHEM10016	NGHEM10017	NGHEM10018
Blue	NGPEM10013	NGPEM10014	NGPEM10015	NGPEM10016	NGPEM10017	NGPEM10018
Blue	NGSEM10013	NGSEM10014	NGSEM10015	NGSEM10016	NGSEM10017	NGSEM10018
Black	NGSEM10043	NGSEM10044	NGSEM10045	NGSEM10046	NGSEM10047	NGSEM10048

2) Disposable Nitrile Gloves (Blue; Black)



3) The object of the declaration described in point 2 is in conformity with the relevant Union harmonisation legislation: **Personal Protective Equipment Regulation (EU) 2016/425**



Document Number : INTCO-PPE-NBR

Version: A/1

4)References to the relevant harmonised standards used, including the date of the standard or references to the other technical specification, including the date of the specification, in relation to which conformity is declared:

Standards/ Technical Specifications applied	EN ISO 21420:2020
	EN ISO 374-1:2016+A1:2018
	EN ISO 374-4:2019
	EN ISO 374-5:2016

5)Where applicable, the notified body SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin 15D15 YN2PIreland Tel:+00353 (0) 1 437 2484; Notified Body Number: 2777 performed the EU examination (Module B) and issued the EU type- examination certificate (Reference to that certificate: 2777/14815-03/E00-00)

6)Where applicable, the PPE is subject to the conformity assessment procedure (either conformity to type based on internal production control plus supervised product checks at random intervals (module C2) or conformity to type based on quality assurance of the production process (module D under surveillance of the notified body: SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin 15D15 YN2PIreland Tel:+00353 (0) 1 437 2484; Notified Body Number: 2777

Signed for and on behalf of	Anhui Intco Medical Products Co., Ltd.
Date of issue	2023.11.14
Name, function	Wang Yazhou, Quality Manager 王玉洲



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:

Disposable Nitrile Exam 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; EN 1041:2008; EN 15223-1:2016

EN 455-1:2020+A1:2022; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009;

ISO 10993-1:2018; ISO 10993-10:2010. 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

Intco references						
Colour	XS	S	M	L	XL	XXL
Blue	NGVEM10013	NGVEM10014	NGVEM10015	NGVEM10016	NGVEM10017	NGVEM10018
Blue	NGBEM10013	NGBEM10014	NGBEM10015	NGBEM10016	NGBEM10017	NGBEM10018
Black	NGBEM10043	NGBEM10044	NGBEM10045	NGBEM10046	NGBEM10047	NGBEM10048
Blue	NGHEM10013	NGHEM10014	NGHEM10015	NGHEM10016	NGHEM10017	NGHEM10018
Blue	NGPEM10013	NGPEM10014	NGPEM10015	NGPEM10016	NGPEM10017	NGPEM10018
Blue	NGSEM10013	NGSEM10014	NGSEM10015	NGSEM10016	NGSEM10017	NGSEM10018
Black	NGSEM10043	NGSEM10044	NGSEM10045	NGSEM10046	NGSEM10047	NGSEM10048

Anhui 2024-04-30

Place , date



Quality Manager

Legally binding signature, Function



ANHUI INTCO MEDICAL PRODUCTS CO., LID

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

To NERI,

We Anhui Intco Medical Products Co,ltd, address: No.6, Haitang South Road,Suixi Wuhu Modern Industrial Park, Suixi County, Huaibei City, Anhui Province, hereby declare that the following INTCO MDR SKU correspond with NERI reference code written on Proforma Invoice. All nitrile articles NERI ordered from INTCO comply with one Declaration of Conformity for Disposable NBR Gloves-MDR, and our Declaration of Conformity for Disposable NBR Gloves-MDR correspond with NERI's reference code written on Proforma Invoice.

Product	INTCO MDR SKU	NERI Product Code
3.0 blue nitrile	NGVEM10013-18	393050
3.5 blue nitrile	NGBEM10013-18	393056
3.5 black nitrile	NGBEM10043-48	393057
4.0 blue nitrile	NGHEM10013-18	393058
4.5 blue nitrile	NGPEM10013-18	393060
5.5 blue nitrile	NGSEM10013-18	393061
5.5 black nitrile	NGSEM10043-48	393062
4.0 blue nitrile	NGHEM20013-18	393059

2024/4/25

ANHUI INTCO MEDICAL PRODUCTS CO., LID



DECLARATION OF CONFORMITY

To Whom It May Concern:

We declare that disposable nitrile gloves produced by Anhui Intco Medical Products Co., Ltd (No.6, Haitang South Road, Suixi Wuhu Modern Industrial Park, Suixi County, Huaibei City, Anhui Province) have undergone the following two food contact tests:

PTC23042503602C-EN01
TAOHG2300382501.

We also declare and certify that our production of disposable nitrile gloves complies with EU Food regulation 1935/2004 and (EC) No. 2023/2006 and tested according to requirements of the Plastic Materials and Articles in contact with food commission follow the new Regulation (EU) No. 10/2011 of 13th April, 2020.

Product	INTCO MDR SKU	NERI Product Code
3.0 blue nitrile	NGVEM10013-18	393050
3.5 blue nitrile	NGBEM10013-18	393056
3.5 black nitrile	NGBEM10043-48	393057
4.0 blue nitrile	NGHEM10013-18	393058
4.5 blue nitrile	NGPEM10013-18	393060
5.5 blue nitrile	NGSEM10013-18	393061
5.5 black nitrile	NGSEM10043-48	393062
4.0 blue nitrile	NGHEM20013-18	393059

Department: Quality
Person: Andy Wang
Title: QM
Date: 2024.5.9
Signature: Andy Wang

