



Document Number : INTCO-CE-DC-NBR-001

Version: A/0

## EU DECLARATION OF CONFORMITY

### Manufacturer

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

*Address:* (Haitang road west and yinhua road north) Suixi Wuhu Modern Industrial Park ,Suixi Town, Huaibei City, Anhui Province, P. R. China..

**SRN:**

Declares that the MDR described hereafter

*Product name and model:*

**Disposable Nitrile (NBR) Gloves**

**UMDNS code: 11882**

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

**UDI-DI:**

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



This Declaration of conformity is valid for five years: 7 / APR / 2020 to 6 / APR / 2025. If there is a change in the declaration information, this declaration is invalid.

The above mentioned declaration of conformity is exclusively under the responsibility of

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

**Address:** (Haitang road west and yinhua road north) Suixi Wuhu Modern Industrial Park ,Suixi Town, Huaibei City, Anhui Province, P. R. China..

Anhui 2020-04-07

Place , date

  
Chi Yongtao Plant manager

Legally binding signature, Function



中国认可  
国际互认  
检测  
TESTING  
CNAS L0604

# Test Report

No.: QDHL2004003646MD

Date: MAY.18,2020

Page: 1 of 2

ANHUI INTCO MEDICAL PRODUCTS CO,LTD  
NO.1 HAITANG ROAD,SUIXI DISTRICT ECONOMIC  
DEVELOPMENT AREA,HUAIBEI CITY,ANHUI PROVINCE.

The following sample(s) was/were submitted and identified by the client as:

Sample Description	: DISPOSABLE NITRILE GLOVE(NBR)
Lot No.	: NOT PROVIDED
Lot Size	: NOT PROVIDED
Sample Quantity	: 220PCS
Sample Receiving Date	: APR.29,2020
Testing Period	: APR.29,2020 TO MAY.18,2020
Test Performed	: SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested	: BS EN 455-1:2000 MEDICAL GLOVES FOR SINGLE USE – PART 1: REQUIREMENTS AND TESTING FOR FREEDOM FROM HOLES (CLAUSE 5.1)
Test Result(s)	: PLEASE REFER TO THE FOLLOWING PAGE(S)
Conclusion	: THE SUBMITTED SAMPLE MET THE REQUESTED TEST REQUIREMENT.



Remark: Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This document cannot be used for publicity, without prior written approval of the SGS.

SGS-CSTC Standards  
Technical Services (Qingdao)  
Co., Ltd.

*Jessica Gao*



Jessica Gao  
Approved Signatory

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Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755)83071443, or email: cn\_dqc@sgs.com

## Test Report

No.: QDHL2004003646MD

Date: MAY.18,2020

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### Test Conducted:

**BS EN 455-1:2000 Medical gloves for single use – Part 1: Requirements and testing for freedom from holes**

Number of test sample	:	200 Pieces
Number of non-conforming gloves	:	0

Clause	Test Items	Result
5	Watertightness test for detection of holes	---
5.1	Referee testing	Pass (See note 1)

Note : 1 Sample quantity: 200pcs, AQL:1.5, Ac:10, Re:11, Found:0.  
The sample selecting amount for this clause is deviated to 200 pcs as assessed by SGS.

Remark: The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

### Sample Photo:

Received sample



SGS authenticate the photo on original report only

\*\*\*End of Report\*\*\*



Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755)81071443, or email: CH.Boeckebach@sgs.com

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