

## ØRN Nitrile Disposable Gloves



<b>PRODUCT:</b>	<b>OH1502 - Nitrile Disposable Gloves</b>
<b>DESCRIPTION:</b>	<ul style="list-style-type: none"> <li>✓ <b>Nitrile</b></li> <li>✓ <b>Powder Free</b></li> <li>✓ <b>Blue</b></li> <li>✓ <b>Made of high-quality Nitrile.</b></li> <li>✓ <b>Textured</b></li> <li>✓ <b>Ambidextrous</b></li> <li>✓ <b>EN455 1,2,3</b></li> <li>✓ <b>EN ISO 374 1,5</b></li> <li>✓ <b>CE</b></li> </ul>
<b>ATTRIBUTES</b>	<ul style="list-style-type: none"> <li>✓ Manufactured from nitrile butadiene.</li> <li>✓ Latex-free reducing the risk of hypersensitivity and allergic reactions.</li> <li>✓ Low in residual chemical to reduce the risk of contact dermatitis associated with these chemicals.</li> <li>✓ Flexible material for improved feel and for reducing fatigue during extended wear.</li> <li>✓ Tear resistant providing greater durability compared to latex or vinyl.</li> <li>✓ Beaded cuff for added strength and easier wearing.</li> <li>✓ Powder-free to reduce potential dust contamination.</li> <li>✓ Textured to improve grip.</li> </ul>
<b>REGULATORY COMPLIANCE:</b>	<ul style="list-style-type: none"> <li>• Manufactured in accordance with European Medical Devices Directive 93/42/EE CE Category: Cat I.</li> <li>• EN455-1:2000 part 1: Medical gloves for single use. Requirements and testing for freedom from holes.</li> <li>• EN 455-2:2015 Medical gloves for single use part 2: Requirements and testing for physical properties.</li> <li>• EN 455-3:2015 Medical glove for single use part 3: Requirements and testing for biological evaluation.</li> <li>• EN ISO 374-1:2016 and EN ISO 374-5: 2016 protection against bacteria, fungi and viruses.</li> <li>• Tested to: AQL 1.5.</li> <li>• Visually inspected for holes and minor defects.</li> <li>• Typical force at break: 6 Newtons.</li> <li>• Shelf life of 3 years.</li> <li>• Average thickness of wrist is 0.05mm, palm is 0.065mm and finger is 0.085mm.</li> </ul> <p>All certification is registered to Weihai Dishang Medical Technology Co, Ltd. who manufacture the product for ØRN (Int) Limited.</p>
<b>ØRN PRODUCT CODE:</b>	OH1502

## ØRN Nitrile Disposable Gloves

<b>COLOUR:</b>	Blue
<b>SIZES:</b>	S, M, L, XL
<b>PACKAGING:</b>	100 gloves per box / 10 Boxes per Carton (1000 gloves per carton)
<b>SHELF LIFE</b>	3 Years
<b>WASHING INSTRUCTIONS:</b>	Non-Reusable – Single Use Gloves
<b>COUNTRY OF MANUFACTURE:</b>	China
<b>COMMODITY CODE:</b>	4015110000
<b>MANUFACTURED FOR ØRN HEALTH BY:</b>	The Dishang Group 186 West Wenhua Road Weihai Shandong 264209 CHINA
<b>MANUFACTURERS PRODUCT CODE:</b>	BS020-N01
<b>IMPORTANT NOTICE:</b>	<p>This guide is only an outline. It should not be used as the only means for selecting protective clothing. Before using any protective clothing, the wearer must read and understand the user instructions for each product.</p> <p>Specific country legislation must be observed. If in doubt, contact a safety professional. Selection of the most appropriate PPE will depend on the situation and should only be made by a competent person knowledgeable of the actual working conditions and the limitations of PPE.</p> <p>Final determination as to the suitability of these products for a particular situation is the employer's responsibility.</p> <p>This information is subject to revision at any time. Always read and follow instructions.</p>
<b>LIMITATION OF LIABILITY:</b>	Except as provided above, Dishang Medical Nor ØRN (Int) Limited shall not be liable or responsible for any loss or damage, whether direct, indirect, incidental, special or consequential arising out of the sale, use or misuse of this product, or the user's inability to use such products.
<b>ØRN HEALTH REGISTERED ADDRESS</b>	<p><b>ØRN International</b> Unit A, Tingewick Road Industrial Park Buckingham MK18 1SU</p> <p>O1295 221357 sales@ornhealth.com</p>

## ØRN Nitrile Disposable Gloves





ØRN Nitrile Disposable Gloves



Notified Body responsible for certification and on going conformity: SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin 15D15 YN2P,Ireland(:2777)

POWDER FREE 100 PCS NON STERILE

CAUTION

These gloves are sometimes subject to failure and may puncture or tear if donned improperly. Discontinue use if damaged. Not intended for use as a chemical barrier. Store in a cool place, avoid excessive heat 40°C(104°F). Do not store in highly humid or damp areas. Shield open box from direct sun, fluorescent lighting, or excess ozone conditions. Primary material-Synthetic Nitrile Rubber(Nitrile). Does not contain natural rubber latex. Components used in making gloves may cause allergic reactions in some users. The buyer & user have examined these gloves after having read the cautionary statements, and have determined them to be fit for the purpose of general purpose and cleaning in non-sterile environments. The manufacturer, its resellers, agents & their employees are not responsible for any other claims or representations. No warranty implied.

ØB: Examinációs kesztyű, Nitril, Pormentes, nem-sterilis, antistatisztikus. Szőrzet: 5-40°C védelem a hő, az éles, a szilárd és a szilárd. BARSZ: Rukavice za pregled, nitril, bez praška, neobolešljiva, antistatična. Skladnja: 5-40°C, zaštita od topline, vlage, tvrdosti i ozona. BGR: Прегледна ръкавица, нитрил, без прах, необозлежлива, антистатична. Предназначена за медицинска и за обща употреба. Дълготраен: 5-40°C, защита от топлина, влага, твърдост и озон. CZE: Vykřetovací rukavice, nitril, nepraškové, neantistatické. Skladování: 5-40°C chrání před teplem, vlhkostí, tvrdostí a ozonem. DE: Untersuchungshandschuh, Nitril, pulverfrei, antistatisch, antistatisch. Aufbewahrung: 5-40°C. Vor Wärme, Feuchtigkeit, Luft und Ozon schützen. DNK: Undersøgelsehandsker, nitril, pulverfrie, antistatiske, antistatiske. Opbevaring: 5-40°C, beskytter mod varme, fugt, tvæthed og ozon. EE: Uurimisvõrre, nitril, pulvritueta, antistatiline, antistatiline. Hoidmine: 5-40°C, kaitseb soojuste, niiskuse, tugevuse ja ozoni eest kahjustusi. ES: Guantes de examen, nitrilo, sin polvo, antistático, antistático. Guardado: 5-40°C protección del calor, la humedad, la rigidez y el ozono. FI: Tutkimukseen nitril, puuvillaton, antistattinen, antistattinen. Säilytys: 5-40°C suojaa lämmöltä, kosteudelta, kovuudelta ja ozonilta. FR: Gants d'examen en nitrile, non poudre, non caustique, antistatique. Stockage: 5-40°C, protégées de la chaleur, de l'humidité, de la rigidité excessive et de l'ozone. GB: Examination nitrile, powder free, antistatic, antistatic. Storage: 5-40°C, protect from heat and moisture. HU: Vizsgálókesztyű, nitril, pormentes, antistatisztikus. Tárolás: 5-40°C védelem a hő, a pára, a szilárd és a szilárd ellen. IT: Guanti da esame, nitrile, non polverizzati, non oleati, antistatici. Conservazione: 5-40°C al riparo da fonti di calore, umidità, luce e ozono. JY: Aardloze handschoenen, nitril, niet-gepoederd, antistatisch, antistatisch. Opslag: 5-40°C. Bescherming tegen warmte, vochtigheid, stijfheid en ozon. LT: Tyrimo pirštai, nitriliniai, be miltelių, antistatiniai, antistatiniai. Saugojimas: 5-40°C. Saugoma nuo šilumos, drėgmės, tvirtumo ir ozono. LV: Pārbaudes cimdi, nitrila, nepulvētieši, antistātiski, antistātiski. Glabāšana: 5-40°C atbilstoši, lai pasargātu, mitrumu, stingrību un ozonu. NL: Onderzoekshandschoenen, nitril, powder, antistatisch, antistatisch. Opslag: 5-40°C, bescherming tegen hitte, vocht, stijfheid en ozon. PL: Rękawiczki przebadawcze, nitrilowe, bezpyłkowe, antystatyczne, antystatyczne. Przechowywanie: 5-40°C, ochrona przed ciepłem, wilgocią, twardością i ozonem. PT: Luvas de exame, de nitrilo, sem pó, não antistáticas, antistáticas. Armazenamento: 5-40°C, proteção de calor, humidade, rigidez e ozono. RO: Mănuși de vizualizare, nitril, fără prașină, antistatic, antistatic. Stocare: 5-40°C, protecție împotriva temperaturii ridicate, umidității, rigidității și ozonului. RU: Перчатки для осмотра, нитриловые, безпыльчатые, антистатические, антистатические. Хранение: 5-40°C. Защищает от жары, влаги, жесткости и озона. SK: Vykřetovací rukavice, nitril, nepraškové, antistatické, antistatické. Úloženie: 5-40°C, ochrana pred teplotou, vlhkosťou, tvrdosťou a ozonom. SRB: Pregledne rukavice, nitril, bez praška, antistatične, antistatične. Čuvanje: 5-40°C, štiti od toplote, vlažnosti, tvrdosti i ozona. SV: Undersökningsskydd, nitril, pulverfritt, antistatiskt, antistatiskt. Förvaring: 5-40°C. Skydd mot värme, fukt, tväthet och ozon. TH: ถุงมือตรวจร่างกาย, นิตริล, ไม่มีฝุ่น, antistatic, antistatic. การเก็บรักษา: 5-40°C. ป้องกันความร้อน, ความชื้น, ความแข็ง และโอโซน. TR: Deneyim eldivleri, nitril, toz yok, antistatik, antistatik. Depolama: 5-40°C. Isi, nemli, sertlik ve ozon kaynakli hasara koruyur. UK: Examination gloves, nitrile, powder free, antistatic, antistatic. Storage: 5-40°C, protect from heat, moisture, rigidity and ozone. US: Examination gloves, nitrile, powder free, antistatic, antistatic. Storage: 5-40°C, protect from heat, moisture, rigidity and ozone. VI: Găng tay khám, nitril, không bụi, antistatic, antistatic. Bảo quản: 5-40°C, bảo vệ khỏi nhiệt độ, độ ẩm, độ cứng và ozon. XN: Examination gloves, nitrile, powder free, antistatic, antistatic. Storage: 5-40°C, protect from heat, moisture, rigidity and ozone. YK: Examinációs kesztyű, nitril, pormentes, antistatisztikus. Tárolás: 5-40°C védelem a hő, a pára, a szilárd és a szilárd ellen. ZH: 检查手套, 丁腈, 无粉, 防静电, 防静电. 储存: 5-40°C, 防止热、湿气、刚性和臭氧。 ZN: Examinációs kesztyű, nitril, pormentes, antistatisztikus. Tárolás: 5-40°C védelem a hő, a pára, a szilárd és a szilárd ellen. ZN: Examinációs kesztyű, nitril, pormentes, antistatisztikus. Tárolás: 5-40°C védelem a hő, a pára, a szilárd és a szilárd ellen.

Weihai Dishang Medical Technology Co.,Ltd. Add: Room 406-409, Block C, No. 213 Torch Road, Torch High-tech Industrial Development Zone, Weihai, Shandong, China. TEL:0086-631-5658211

EC REP Luxus Lebenswelt GmbH Kochstr.1, 47877, Willich Germany TEL: 0049-1715605732 E-mail: info.m@luxuslw.de VIRUS KPT Lot 202101 2021-01 2024-01



## EC Declaration of Conformity

### Directive 93/42/EEC Medical Devices

This is hereby declared that following designated product complied with the essential health and safety requirements of Council Directive 93/42/EEC Medical Devices on the approximation of the laws of the Member States relating to it.

<b>Manufacturer</b>	
<b>Name</b>	Weihai Dishang Medical Technology CO.,Ltd
<b>Address</b>	Room 406-409,Block C,No.213 Torch Road,Torch High-tech Industrial Development Zone,Weihai,Shandong China
<b>Corporate representati ve</b>	David Sun
<b>Declare that the products</b>	
<b>Name</b>	Disposable Nitrile Powder-Free Examination Gloves
<b>Model</b>	BS 020-N01/ BS 020-N03
<b>Standard</b>	EN 455-1:2000, EN 455-2:2015, EN 455-3:2015,EN ISO 374-1:2016; EN ISO 374-5:2016
<b>Classification</b>	-
<b>Test Report No.</b>	7191233436-EEC20/01-WBH_AD1/7191233436-EEC20/03-WBH_AD1
<b>Certificate No.</b>	2777/11521-02/E01-01
<b>Testing Lab Information</b>	<p style="text-align: center;">TÜV SÜD PSB Pte. Ltd 1 Science Park Drive, #02-01 Singapore 118221 Phone : +65-6885 1333 Fax : +65-6776 8670 E-mail: <a href="mailto:enquiries@tuv-sud-psb.sg">enquiries@tuv-sud-psb.sg</a> TÜV SÜD PSB Pte. Ltd.is accredited in accordance with ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories.</p>

This declaration of conformity is issued under the the sole responsibility of the manufacturer.

EC Representative: Luxus Lebenswelt Gmbn kochstr.1,47877 Willich German



Sign: *Eric Wei*

Position: Director

Date Of Issue: 2020/ 08/ 10

\*Remark: This is only an manufacturer's Declaration of Conformity, not the CE certificate.



PSB Singapore

# TEST CERTIFICATE

This Certificate is issued to

Weihai Dishang Medical Technology Co., Ltd.  
21th Floor, No 186 West Wenhua Road,  
Weihai, Shandong,  
264209, China

## FOR

Product: Disposable Nitrile Powder-Free Examination Gloves

Brand/Model: 1. BS 020-N01  
2. BS 020-N03

Product Details: 1. Sizes XS, S, M, L & XL, Powder-Free, Blue, Nitrile, Examination Glove  
2. Sizes XS, S, M & L, Powder-Free, Blue Purple, Nitrile, Examination Glove

Specification: EN 455-1:2000  
EN 455-2:2015  
EN 455-3:2015

Test Report: 1. 7191233436-EEC20/01-WBH\_AD1  
2. 7191233436-EEC20/03-WBH\_AD1

Date of Test Report: 24 Jul 2020

## Summary

A sample of product submitted was tested and found to comply with the requirements of the above standards.

TÜV SÜD PSB Pte Ltd

Certificate No:	Date of Original Issue:	Date of Last Revision:	Date of Expiry:
04147	06 Aug 2020	-	05 Aug 2022

This Certificate is part of a full report and should be read in conjunction with it. This Certificate remains the property of TÜV SÜD PSB Pte Ltd and shall be returned upon request. The use of this Certificate is subjected to the terms and conditions of the Test Certification Scheme.

Note: This Certificate is issued pursuant to the terms set out overleaf.



Issued to:

Weihai Dishang Medical Technology Co Ltd  
Room 406-409, Block C, No. 213  
Torch Road, Torch High-tech  
Industrial Development Zone  
Weihai  
Shandong  
China

Notified Body: 2777

SATRA customer number: P1543

# EU Type-Examination Certificate

**Certificate number: 2777/11521-02/E01-01**

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:

Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

**Product reference:**

**Description:**

DS0102016-DS0102020  
DS0102026-DS0102030  
DS0102036-DS0102040  
DS0102046-DS0102050  
DS0102056-DS0102060

Disposable Powder-Free Nitrile Gloves  
Available Colours in  
Blue  
Blue Purple  
Cobalt Blue  
White  
Black

**Sizes:** 6 – 10 (XS – XL)

**Classification:**

**EN ISO 374-1:2016 /Type B**

40% Sodium Hydroxide (K)  
30% Hydrogen Peroxide (P)  
n-heptane (J)  
25% Ammonium hydroxide (O)  
37% Formaldehyde (T)

**Level**

6  
2  
0  
0  
5

**EN 374-4:2013 Degradation %**

-38.4  
17.6  
27.4  
29.9  
46.6

**EN ISO 374-5:2016**

Protection against Bacteria and Fungi  
Protection against Viruses

**Level**

Pass  
Pass

Standards/Technical specifications applied:

EN 420: 2003+A1: 2009; EN ISO 374-1:2016; EN ISO 374-5:2016

Technical reports/Approval documents:

SATRA: CHT0269325/1814, CHT0269325/1814/SPT, CHT0269325/1814/EN/A, CHT0269325/1814/EN/B/Issue 2, CHT0273567/1830/LH/B, CHT0275700/1838/LH, CHT0269325/1814/EN/C, CHT0273567/1830/LH/A

Signed on behalf of SATRA:

*Daisy He*

Daisy He

*Quincey Brown*

Quincey Brown

**Date of issue:** 02/09/2020

**Expiry date:** 09/11/2023



This is here to certify that

BS 020-N01 Ref. to test report NO. 7191233436-EEC20/01-WBH\_AD1

DS0102016-DS0102020 Ref.to certificate 2777/11521-02/E01-01

are the same products, both refer to Power Free Nitrile Examination Gloves from Dishang Medical Technology Co., Ltd





# Quality Management System Certification

Certificate Code: BMCQ0120088M

This is to certify that

**Weihai Dishang Medical Technology CO., LTD.**

Organization Code: 91371000MA3REQTA0Y

**Registered Address:** Room 406-409, Site C, Chuang xin Base, NO.213 Huoju Road, Torch High Technology Development District, Weihai City, Shangdong Province. **Postcode:** 264200

**Certification Address:** Room 406-409, Site C, Chuang xin Base, NO.213 Huoju Road, Torch High Technology Development District, Weihai City, Shangdong Province. **Postcode:** 264200

This Management System

**GB/T 19001-2016 idt ISO 9001:2015**

## Scope of Certification:

Production and Sales of Disposable Medical Protective Clothing; Production and Marketing of Isolation Gown; Production and Marketing of Disposable Medical Surgical Masks; Production and Marketing of Disposable Medical Masks; Production and Marketing of Surgical Gown/Operating Gown; Sales of Face Shield, Disposable Natural Latex Inspection Gloves, Disposable Medical Vinyl Examination Gloves and Disposable Medical Nitrile Examination Gloves.

Date of issue: 06/28/2020      Date of Surveillance: 08/03/2020      Date of expiry: 06/27/2023

Notes: Within the date of validity, organization must accept the annual confirmation of BENCHMARKS.

This certificate information can be querying in CNCA website: [www.cnca.gov.cn](http://www.cnca.gov.cn) and BENCHMARKS website:

[www.benchmarks.com.cn](http://www.benchmarks.com.cn)

1st Periodical Audit:

2nd Periodical Audit:

3rd Periodical Audit:



*Jody Fu*  
Signer

# Medical Devices Quality Management Systems Certification

Certificate Code: BMCMDQ0120003M

This is to certify that  
**Weihai Dishang Medical Technology CO., LTD.**

Organization Code: 91371000MA3REQTA0Y

**Registered Address:** Room 406-409, Site C, Chuang Xin Base, NO.213 Huoju Road, Torch High Technology Development District, Weihai City, Shangdong Province. **Postcode:** 264200

**Certification Address:** Room 406-409, Site C, Chuang Xin Base, NO.213 Huoju Road, Torch High Technology Development District, Weihai City, Shangdong Province. **Postcode:** 264200

This Management System

certification is valid to the following Standard:

**YY/T 0287-2017 idt ISO 13485: 2016**

**Scope of Certification:**

Production and Sales of Disposable Medical Protective Clothing; Production and Marketing of Isolation Gown; Production and Marketing of Disposable Medical Surgical Masks; Production and Marketing of Disposable Medical Masks; Production and Marketing of Surgical Gown/Operating Gown; Sales of Face Shield, Disposable Natural Latex Inspection Gloves, Disposable Medical Vinyl Examination Gloves and Disposable Medical Nitrile Examination Gloves.

Date of issue: 06/28/2020 Date of Surveillance: 08/03/2020 Date of expiry: 06/27/2023

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1st Periodical Audit:

This certificate information can be querying in CNCA websit: [www.cnca.gov.cn](http://www.cnca.gov.cn) and BENCHMARKS website:

2nd Periodical Audit:

[www.benchmarks.com.hk](http://www.benchmarks.com.hk).

3rd Periodical Audit:



  
Signer