Appendix B, rev0

EU DECLARATION OF CONFORMITY

Manufacturer	CoShield Global Trading Ltd
Address	5 Noel Rodgers Place, Milson, Palmerston North, 4414, New Zealand
Single Registration Number	NZ-MF-000029831
EU Authorized Representative	Wellkang Ltd (for medical device)
Address	Enterprise Hub, NW Business Complex, 1 Beraghmore Road, Derry, BT48 8SE, Northern Ireland
Single Registration Number	XI-AR-000001836
Products covered	See Annex 1

We declare that the non-sterile, powder-free, nitrile examination gloves covered by this declaration and listed in Annex 1, whose intended use is to protect patients, users or third parties against diseases and provide temporary protection against bacteria, fungi, viruses and certain chemicals, can be used in the laboratory, medical and industrial sectors as well as in the domestic area by laypersons and health care users alike, are in conformity as PPE and medical devices with:

PPE Regulation (EU) 2016/425 as amended and with standards EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016 and EN ISO 21420:2020.

SATRA Technology Europe Limited (Notified Body N° 2777) performed the EU type-examination (Module B) and issued the EU type-examination certificate N° (to be included later) for category III PPE,

is subject to the conformity assessment procedure set out in Module C2 of Regulation (EU) 2016/425 under the supervision of SATRA Technology Europe Limited, Bracetown Business Park, Clonee, Dublin 15 D15 YN2P, Republic of Ireland (Notified Body N° 2777).

CE 2777

and

Medical Device Regulation (EU) 2017/745 as amended and with standards EN 455-1:2020, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009 and are Class I self-certified according to Annex VIII, Rule 1 and 5 and are subject to conformity assessment procedure using technical documentation according to Annex II and Annex III

CE

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

Done at New Zealand, on 20 November 2022.

Caleb Hall
Managing Director
CoShield Global Trading Ltd

ANNEX 1

Model names	Product names	GMDN code
No Ordinary Gloves	NG-NOMD32-000 (size XXS)	56286
No Ordinary Gloves	NG-NOMD32-001 (size XS)	56286
No Ordinary Gloves	NG-NOMD32-002 (size S)	56286
No Ordinary Gloves	NG-NOMD32-003 (size M)	56286
No Ordinary Gloves	NG-NOMD32-004 (size L)	56286
No Ordinary Gloves	NG-NOMD32-005 (size XL)	56286
No Ordinary Gloves	NG-NOMD32-006 (size XXL)	56286

No Ordinary® Medical Gloves

The No Ordinary® Gloves is manufactured in Asia and distributed Globally.
The manufacturing facility is certified to quality and social compliance standards, ISO 13485, ISO 9001, and Sedex approved.

This world-class medical examination glove is suited to the healthcare industries due to the high tensile strength and elasticity, complete testing for use with Chemotherapy drugs, and meeting globally recognised performance standards. The absense of a powdering agent reduces the occurance of allergies and the dryness of skin on the hands.

Multi-Purpose

Hospital · Dental · Laboratory · Hotel · Industry · Cleaning · Food · Cosmetic

Technical Data Sheet

Type	Powder Free, Industrial Glove
Specification	Non-Sterile/Disposable
Cuff	Beaded
Colour	Blue
Internal Surface	Clorinated
External Surface	Finger textured
Primary	Nitrile
Packaging	100~200pcs/box – 10 boxes/carton

Size	Weight Per Size	Width (mm/inch)	Product Code	
			100 pcs/box	200 pcs/box
Extra Small	2.5g ± 0.3g	≤ 79 / 3.3	NG-NOMD32-001	NG-NOMD32-201
Small	2.9g ± 0.3g	80 ± 5 / 3.3 ± 0.2	NG-NOMD32-002	NG-NOMD32-202
Medium	3.2g ± 0.3g	95 ± 5 / 3.7 ± 0.2	NG-NOMD32-003	NG-NOMD32-203
Large	3.5g ± 0.3g	110 ± 5 / 4.1 ± 0.2	NG-NOMD32-004	NG-NOMD32-204
Extra-Large	3.8g ± 0.3g	≥110 / 4.1	NG-NOMD32-005	NG-NOMD32-205

Product Characteristics

Characteristics	Typical values*
Length (mm/in)	≥ 240 / 9.45
Thickness (mm/in) - Finger	≥ 0.06 / 3 mil
Thickness (mm/in) - Palm	≥ 0.05 / 2 mil
Freedom from holes	AQL 1.0%
(Before accelerated ageing)	
Force at break - (N)	≥ 6.0
Tensile Strength - (MPa)	≥14
Ultimate elongation (%)	≥ 500
(After accelerated aging at (70±2˚C 166±2 hr)).	
Force at break - (N)	≥6.0
Tensile Strength - (MPa)	≥14
Ultimate elongation (%)	≥400
Powder Control (mg/glove)	≤2.0

** Values reported as average, actual results may vary due to the nature of the manufacturing process*

Chemotherapy Drug Permeation Resistance Tested

Characteristics	Avg. Time in minutes
Cisplatin, 1.0 mg/ml (1,000 ppm)	>240
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	>240
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	>240
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	>240
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	>240
Fluorouracil, 50.0 mg/ml (50,000 ppm)	>240
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	>240
Vincristine Sulfate, 1.0 mg/ml(1,000 ppm)	>240
Mechlorethamine HCl, 1.0mg/ml(1,00 ppm)	>240
Methotrexate, 25.0mg/ml(25,000ppm)	>240
Mitomycin C,05 mg/ml(500ppm)	>240
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)*	10.2
Thiotepa, 10,0mg/ml (10,000 ppm)*	40.5

**Not recommended for use of drugs*

Product Standards

US Standards	
ASTM D6319	Physical Properties & Dimensions
ASTM F1671	Viral Penetration
ASTM D6978	Tested for use with Chemotherapy Drugs
ASTM D6978	Tested for use with Fentanyl

EU Standards	
EN 455-1	Physical Properties & Dimensions
EN 455-2	Testing for Physical properties
EN 455-3	Testing for Biological evaluation
EN 455-4	Testing of Shelf life
EN 374-1	Chemical & Micro-organism Permeation
EN 374-2	Determination of resistance to penetration
EN 374-4	Determination of resistance to degradation by chemicals
EN 374-5	Terminology and performance requirements for micro-organisms risks
EN 21420:2020	EU PPE Glove Standards
EN 16523-1:2015+A1:2018	Determination of resistance to permeation by liquid chemicals

Regulatory Approvals
PPE Category III (EU)
MDD, Class I
FDA - 510(k)
TGA

AQL 1.0 · MD

User instruction

The instruction below should be used in conjunction with detailed information on the packaging.

Short description of the product

Nitrile examination, powder-free, non-sterile for disposable use. Product reference “No Ordinary Medical Gloves”

Full description of the product

Raw material	: nitrile
External surface	: textured
Internal surface	: polymerized + chlorinated
Cuff	: beaded
Colour	: blue
Shape	: ambidextrous, fitting to the right and left hand
Size range	: XS (5-6), S (6-7), M (7-8), L (8-9), XL (9-10), XXL (10-11)
AQL	: 1.0
Quantity in packaging	: 100 pcs. by weight
Shelf life	: 3 years (from the date of manufacturing)

Storage instructions

It is recommended to store the gloves in dry place, in the temperature of 5-35°C and to protect them against direct sunlight and fluorescent light.
Keep the gloves in a distance of not less than 1m from heating devices, sources of fire and ozone.
Do not keep in direct vicinity of solvents, oils, fuels and lubricants.

Food contact

Gloves are marked with food contact symbol and comply with the requirements of European Regulation (EC) No 1935/2004 on materials, European Commission Directive 93/11/EEC and Council of Europe Resolution AP (2004) 4 and with requirement of Regulation (EC) No 2023/2006 on Good Manufacturing Practice.

Result Summary: Test Requested Council of Europe Resolution AP (2004) 4

Extraction conditions (tested for 0.5 hrs in 40°C)	Test Result (limit < 10 mg/dm²)
3% Acetic acid	Pass
10% Ethanol	Pass
20% Ethanol	Pass
50% Ethanol	Pass
Rectified Olive oil	Pass

It can be ensured that no substances are transferred to the food which may lead to an alteration of the food. Food disposable gloves are designed for short-term use and frequent changes. It's best to change your gloves regularly.

MDR classification & compliance

Gloves are classified as class I Medical Device as per MDR 2017/745 and comply to standards: EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2016, EN 1041:2008+A1:2013.

CE marking; CE

PPE classification & compliance

Gloves are category III Personal Protective Equipment as per Annex II of the Regulation 2016/425 and comply to standards: EN ISO 21420: 2020, EN ISO 374-1:2016+ A1:2018 (Type B), EN ISO 374-2:2013, EN16523-1:2015+ A1:2018, EN ISO 374-4:2013, EN ISO 374-5:2016.
EU Type Examination Certificate issued by: SATRA (Notified Body No. 2777)

Checking of PPE manufactured:

CE 2777

SATRA Technology Europe Limited.
Bracetown Business Park.
Clonee.
D15YN2P.
Republic of Ireland.

Declaration of Conformity and Instruction of Use with the information about the importer are available at: www.noordinarygloves.com

Permeation performance levels as per EN ISO 374-1:2016+ A1:2018 Level1>10min , Level2>30 min, level3>60 min, level4>120min,Level5>240min, Level6>480min Test results acc. to EN 16523-1:2015+ A1:2018		EN ISO 374-4:2019 Degradation [%]
Chemical	Level	
35% Ethanol	6	55.0
40% Isopropanol	6	68.7
10%Acetic acid	4	53.5
50% Benzalkonium chloride*	6	29.5
4% Chlorhexidine digluconate **	6	32.9
10% Phosphoric acid	6	14.0
40% Sodium hydroxide (K)	6	2.6
12% Sodium hypochlorite	6	22.7
50% Sulphuric Acid	6	21.1
5% Ethidium Bromide	6	32.9
3% Hydrogen peroxide	6	44.0
30% Hydrogen peroxide (P)	2	52.8
37% Formaldehyde (T)	5	20.0
50% Glutaraldehyde	6	22.9
0.1% Phenol	6	24.7

* Permeation rate 5 µg/cm²/min, EN ISO 374-4:2019 degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.
** Permeation rate 7 µg/cm²/min, EN ISO 374-4:2019 degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.
Noted : 1) Glove minimum length for Lab application accordance to EN 455-2

Test acc. To EN ISO 374-2:2019 (ISO 2859)	
Performance level	AQL
Level 3	< 0.65
Level 2	< 1.5
Level 1	< 4.0

Test acc. To EN ISO 374-5:2016	
Protection against bacteria & fungi	Pass
Protection against viruses	Pass

Intended use

These are non-sterile powder free nitrile examination and protective gloves for single use, intended for medical purpose that in worn on the hand to protect patient and examiners from cross contamination, conducting medical examinations, diagnostic and therapeutic procedures.
Examination glove is intended for medical activities except surgery. Non-sterile powder free nitrile examination and protective gloves designed and manufactured to be worn or held by a person for protection against one or more risks to that person’s health or safety.
Intended for food contact purposes that donning to prevent the likelihood of food contamination during the preparation or handling and applies to every food handler.
Gloves are classified as Medical Devices Class I. Their design and labelling correspond to the requirements of the European Medical Device Regulation 2017/745, the European Regulation 2016/425 on Personal Protective Equipment and comply with the requirements of European Regulation (EC) No 1935/2004 on materials. Gloves should be used solely according to their intended application.

Components / hazardous components

Some gloves may contain components known to be a possible cause of allergy for person allergic to them, who may develop contact irritation and/or allergic reaction. In case of an allergic reaction, seek medical assistance immediately.

Disposal

Used gloves can be contaminated with contagious or other hazardous substances. They should be disposed of in accordance with local regulation. Gloves should be buried or burned under controlled conditions.

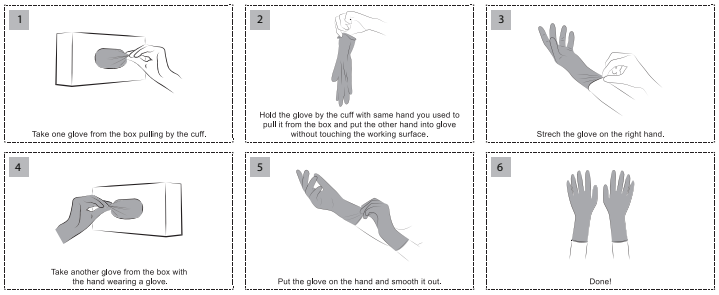
Precautions and indications for use

Dry hands before putting the gloves on. Before usage, inspect the gloves for any defect or imperfections. Use at least 1 pair of gloves for one patient and one procedure, these are disposable gloves. Do not let chemical substances get under the gloves through the cuff. If a chemical substance reaches the skin, wash it away immediately with plenty of water with soap. If the gloves get punctured, torn or broken during their use, take them off and put on the new ones. Avoid using gloves dirty in the inside as they may cause irritation leading to skin inflammation or more serious damages. The gloves should not be used in contact with open fire and to protect against any sharp tools. The gloves are not intended for welding, electric shock protection, ionizing radiation or from the effect of hot or cold objects.
This information does not reflect the actual duration of protection in the workplace and the between mixtures and pure chemicals.
Degradation results indicate the change in puncture resistance of the gloves after exposure to the challenge chemical. The chemical penetration resistance has been assessed under laboratory conditions from samples taken from the palm only (except in case where glove is equal to or over 400 mm – where the cuff is tested also) and relates only to the chemical tested and to the tested specimen. It can be different if the chemical is used in a mixture.
The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen. It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on the temperature, abrasion and degradation.
When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves. Gloves are suitable for special purposes as they are examination gloves where risk of injury to the wrist is considered to be minimal, gloves are shorter than EN ISO 21420 min. length requirement.

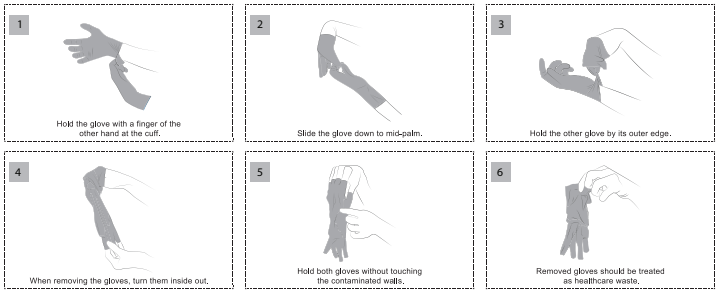
Symbols used on the packaging

MD	Medical Devices	PPE	Personal Protective Equipment	NITRILE	Nitrile Gloves
	Powder-free gloves		For single use only	NON STERILE	Non-sterile
	Product quality is not ensured if the package is damaged		Keep away from sunlight		Keep dry
5°C 35°C	Temperature limitation 5-35°C	ISO 374-1/TYPE B KPT	EN ISO 374-1 chemical protection gloves; accompanied by a 3-digit code referring to three	ISO 374-5:2016 VIRUS	EN ISO 374-5 Glove protecting against bacteria, fungi and viruses
	Consult instructions for use	REF	Catalogue number	LOT	Lot / batch number
	Date of manufacture		Expiry date		Manufacturer
O_3	No Ozone	EC REP	EC Rep symbol should be used with name and address of EC representative	CE	CE Mark, MDR
CE 2777	CE Mark, PPE		Suitable for food contact (for details check the Intended use)		Package can be treated as municipal waste
		21 PAP 20 PAP	Recyclable packaging		

How to put the gloves on



How to take the gloves off



Manufacturer

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Search for EU Declaration of Conformity at www.noordinarygloves.com