



VERIDIA

Certification Pack.

Nitrile Gloves Powder Free.



This pack contains
TGA Certificate
Specification Sheet

Date Released

September 2021



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

JBD Holdings Pty Ltd

for approval to supply

**JBD Holdings Pty Ltd - Nitrile examination/treatment glove,
non-powdered**

ARTG Identifier	368391
ARTG Start Date	7/06/2021
Product Category	Medical Device Included Class 1
GMDN	56286
GMDN Term	Nitrile examination/treatment glove, non-powdered
Intended Purpose	To be worn over the hands as a protective barrier

Manufacturer Details	Address	Certificate number(s)
Intco Medical HK Co Ltd	Level 54 Hopewell Centre 183 Queen's Road East , Hong Kong , China	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Nitrile examination/treatment glove, non-powdered

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 368391
ARTG Start Date: 7/06/2021

3.5g Blue Nitrile Examination Gloves

Standard Cuff, Powder Free



Key Facts

Accreditations:

European Personal Protective Equipment Directive 89/686/EEC

Medical Device Directive 93/42/

EEC Class 1 (2007/47/EC)

EN455-1,2,3,4-Medical Gloves for Single Use

EN420 Protective Gloves; General Requirements

EN374-1,2,3,4,5-Determination of Resistance to Water Penetration.

Leak test passed.

ISO 9001

ISO 13485

Description

- » Examination gloves
- » Ambidextrous
- » Beaded Cuff - providing additional strength and preventing liquid roll off
- » Latex Free - to reduce the risk of hypersensitivity and allergic reactions
- » Powder Free
- » Nitrile Soft Gloves are a softer and thinner for mulation for improved feel and sensitivity, with Micro Textured fingers for excellent wet and dry grip
- » Superior barrier protection over latex and vinyl
- » Excellent puncture resistance and strength

Ordering Information

Code	Description	Size	Qty per inner	Qty per carton	Inners per carton
01-1230-02-02	3.5g Blue Nitrile Gloves - Powder Free	S	200	2000	10
01-1230-02-03	3.5g Blue Nitrile Gloves - Powder Free	M	200	2000	10
01-1230-02-04	3.5g Blue Nitrile Gloves - Powder Free	L	200	2000	10
01-1230-02-05	3.5g Blue Nitrile Gloves - Powder Free	XL	200	2000	10

Dimensions

Palm Size	Palm Width	MGM Length	ASTM D357805 Length (mm)
S	80-99	Min.240	Min.230
M	90-99	Min.240	Min.230
L	100-109	Min.240	Min.230
XL	110-119	Min.240	Min.230

Test Results

Test Type	Inspection Level	AQL
Watertight test	G1	1.5
Watertight test	G1	2.5
Minor defects	G1	4.0
Dimensions	S2	4.0
Physical properties	S2	4.0

Thickness

Measurement type	Single wall (mm)
Finger	Min.0.08
Palm	Min.0.06
Cuff	Min.0.05

Physical Properties

Property	Before Aging	After Aging
Tensile strength	Min. 14	Min. 14
Elongation (%)	Min. 500	Min. 400
Force at Break	Min. 6.0	Min. 6.0

Symbols:



Approved by:

