

COQ Ref No: PTSG-IND0666

CERTIFICATE OF QUALITY

Product Name

9" (4 mil) Powder Free Nitrile Textured Examination Glove Blue

Description

9" (4 mil) Powder Free Nitrile Textured Examination Glove Blue

Catalog No

82026-423

Lot Number

PT18N001

Date Of Manufactur

October 2018

Product Shelf Life

September 2023

Country Of Origin

INDONESIA

Quality System Compliance :

Products are manufactured under FDA510K, ISO 9001:2008, ISO 13485:2003I, CMDCAS Quality

System standard and Good Manufacturing Practices. Products are Inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP. Inspection records are reviewed and signed off by qualified

personnel for product release.

QC Testing

Representative production samples are collected and inspected in

Accordance with current applicable product specification: Meet or exceed ASTM D6319 and ISO 2859 (Sampling table)

Accuracy

Water tight test

Inspection level = G1; AQL 1.5

Visual inspection

Inspection level = G1; AQL 1.5 (critical defects)

AQL 2.5 (major defects)

AQL 4.0 (minor defects)

Dimensional

Inspection level = S2; AQL 4.0

This product is Class I category device as defined by the FDA in 21CFR Parts 807 sub parts C

Physical Property

Inspection level = S2; AQL 4.0

Powder Content

Inspection level = 5pieces; Average ≤ 2 mg/glove

Moisture Content

Inspection level = 5pieces; Average ≤ 1%

Glove count

Inspection level = 5 dispensers; Tolerance 100+/-2 pieces

Product Specification

Material **BSE/TSE Statement** Nitrile Butadiene Rubber

Non-Pyrogenic Statement

N/A

N/A

Dnase & RNase Free Statement:

N/A

Cytotoxicity Statement

N/A

Latex Statement

This product is not made with natural rubber latex

Signed:

PT. SMART GLOVE INDONESIA

JL PELITA RAYA NO 5-7, KAWASAN INDUSTRI MEDAN STAN JL RAYA MEDAN LIPUK PAKAM KM 19, TANJUNG MORAWA B TANJUNG MORAWA, DELI SERDANG, KODE POS 20362 SUMATERA UTARA, INDONESIA.

Poppy Farahrosa QA/RA .Manager



COO Ref No: PTSG-IND0667

CERTIFICATE OF QUALITY

Product Name

9" (4 mil) Powder Free Nitrile Textured Examination Glove Blue

Description

9" (4 mil) Powder Free Nitrile Textured Examination Glove Blue

Catalog No

82026-424

Lot Number

PT18N002 & PT18N003

Date Of Manufactur

October 2018

September 2023

Product Shelf Life Country Of Origin

INDONESIA

Quality System Compliance:

personnel for product release.

Products are manufactured under FDA510K, ISO 9001:2008, ISO 13485:2003I, CMDCAS Quality System standard and Good Manufacturing Practices. Products are Inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP. Inspection records are reviewed and signed off by qualified

QC Testing

Representative production samples are collected and inspected in

Accordance with current applicable product specification: Meet or exceed ASTM D6319 and ISO 2859 (Sampling table)

Accuracy

Water tight test

Inspection level = G1; AQL 1.5

Visual inspection

Inspection level = G1; AQL 1.5 (critical defects)

AQL 2.5 (major defects)

AQL 4.0 (minor defects)

Dimensional

Inspection level = S2; AQL 4.0

Physical Property

Powder Content

Inspection level = S2; AQL 4.0

Inspection level = 5pieces; Average ≤ 2 mg/glove

Moisture Content

Inspection level = 5pieces; Average ≤ 1%

Glove count

Inspection level = 5 dispensers; Tolerance 100+/-2 pieces

Product Specification

This product is Class I category device as defined by the FDA in 21CFR Parts 807 sub parts C

Material

Nitrile Butadiene Rubber

BSE/TSE Statement

N/A

Non-Pyrogenic Statement

N/A

Dnase & RNase Free Statement:

N/A

Cytotoxicity Statement

N/A

Latex Statement

This product is not made with natural rubber latex

Signed:

PT. SMART GLOVE INDONESIA
L PELMI RAYA NO 5-7, KAWASAN INDUSTRI MEDAN STAN.
RAYA MEDAN-LUPUK PAKAM KM 19, TANJUNG MORAWA E
TANJUNG MORAWA, DELI SERDANG, KODE POS 20362 SUMATERA UTARA, INDONESIA

Poppy Farahrosa QA/RA .Manager



COO Ref No: PTSG-IND0668

CERTIFICATE OF QUALITY

Product Name

9" (4 mil) Powder Free Nitrile Textured Examination Glove Blue 9" (4 mil) Powder Free Nitrile Textured Examination Glove Blue

Description Catalog No

82026-426

Lot Number

PT18N004 & PT18N005

Date Of Manufactur

Product Shelf Life

October 2018 September 2023

Country Of Origin

INDONESIA

Quality System Compliance :

Products are manufactured under FDA510K, ISO 9001:2008, ISO 13485:2003I, CMDCAS Quality

System standard and Good Manufacturing Practices. Products are Inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP. Inspection records are reviewed and signed off by qualified

personnel for product release.

QC Testing

Representative production samples are collected and inspected in

Accordance with current applicable product specification: Meet or exceed ASTM D6319 and ISO 2859 (Sampling table)

Accuracy

Water tight test

Inspection level = G1: AQL 1.5

Visual inspection

Inspection level = G1; AQL 1.5 (critical defects)

AQL 2.5 (major defects) AQL 4.0 (minor defects)

Dimensional

Inspection level = S2; AQL 4.0

Physical Property

Inspection level = S2; AQL 4.0

Powder Content

Inspection level = 5pieces; Average ≤ 2 mg/glove

Moisture Content

Inspection level = 5pieces; Average ≤ 1%

Glove count

Inspection level = 5 dispensers; Tolerance 100+/-2 pieces

This product is Class I category device as defined by the FDA in 21CFR Parts 807 sub parts C

Product Specification

Material

Nitrile Butadiene Rubber

BSE/ TSE Statement

N/A N/A

Non-Pyrogenic Statement

Dnase & RNase Free Statement:

N/A

Cytotoxicity Statement

N/A

Latex Statement

This product is not made with natural rubber latex

Signed:

PT. SMART GLOVE INDONESIA
JL PELITA RAYA NO 5-7, KAWASAN INDUSTRI MEDAN STANIL RAYAMEDAN SUPUK PAKAM KM 19, TANJUNG MORAWA B
TANJUNG MORAWA, DELI SERDANG, KODE POS 20362
SUMATERA UTARA, INDONESIA.

Poppy Farahrosa QA/RA .Manager



COQ Ref No: PTSG-IND0669

CERTIFICATE OF QUALITY

Product Name

9" (4 mil) Powder Free Nitrile Textured Examination Glove Blue 9" (4 mil) Powder Free Nitrile Textured Examination Glove Blue

Description Catalog No

Lot Number

82026-428

Date Of Manufactur

PT18N006 & PT18N007

Product Shelf Life

October 2018

Country Of Origin

September 2023 **INDONESIA**

Quality System Compliance:

Products are manufactured under FDA510K, ISO 9001:2008, ISO 13485:2003I, CMDCAS Quality

System standard and Good Manufacturing Practices. Products are Inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP. Inspection records are reviewed and signed off by qualified

personnel for product release.

QC Testing

Representative production samples are collected and inspected in

Accordance with current applicable product specification: Meet or exceed ASTM D6319 and ISO 2859 (Sampling table)

Accuracy

Water tight test

Inspection level = G1; AQL 1.5

Visual inspection

Inspection level = G1; AQL 1.5 (critical defects)

AQL 2.5 (major defects) AQL 4.0 (minor defects)

Dimensional

Inspection level = S2; AQL 4.0

Physical Property

Inspection level = S2; AQL 4.0

Powder Content

Inspection level = 5pieces; Average ≤ 2 mg/glove

Moisture Content

Glove count

Inspection level = 5pieces; Average ≤ 1% Inspection level = 5 dispensers; Tolerance 100+/-2 pieces

Product Specification

This product is Class I category device as defined by the FDA in 21CFR Parts 807 sub parts C

Material

Nitrile Butadiene Rubber

BSE/TSE Statement

N/A

Non-Pyrogenic Statement

N/A

Dnase & RNase Free Statement:

N/A

Cytotoxicity Statement

N/A

Latex Statement

This product is not made with natural rubber latex

Signed:

PT. SMART GLOVE INDONESIA

PLITA RAYANO 5-7, KAWASAN INDUSTRI MEDAN STAN, REMAMEDAN-LUPUK PAKAM KM 19, TANJUNG MORAWA B TANJUNG MORAWA, DELI SERDANG, KODE POS 20362.

SUMATERA UTARA, INDONESIA.

POPPY FARABITOSA

QA/RA .Manager



COO Ref No: PTSG-IND0670

CERTIFICATE OF QUALITY

Product Name

9" (4 mil) Powder Free Nitrile Textured Examination Glove Blue

Description

9" (4 mil) Powder Free Nitrile Textured Examination Glove Blue

Catalog No

82026-424

Lot Number

Date Of Manufactur

PT18L302 & PT18L303

Product Shelf Life

September 2018

Agustus 2023

Country Of Origin

INDONESIA

Quality System Compliance :

Products are manufactured under FDA510K, ISO 9001:2008, ISO 13485:2003I, CMDCAS Quality

System standard and Good Manufacturing Practices. Products are Inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP. Inspection records are reviewed and signed off by qualified personnel for product release.

QC Testing

Representative production samples are collected and inspected in

Accordance with current applicable product specification: Meet or exceed ASTM D6319 and ISO 2859 (Sampling table)

Accuracy

Water tight test

Inspection level = G1; AQL 1.5

Visual inspection

Inspection level = G1; AQL 1.5 (critical defects)

AQL 2.5 (major defects) AQL 4.0 (minor defects)

Dimensional

Inspection level = S2; AQL 4.0

Physical Property

Inspection level = S2; AQL 4.0

Powder Content

Inspection level = 5pieces; Average ≤ 2 mg/glove

Moisture Content

Inspection level = 5pieces; Average ≤ 1%

Glove count

Inspection level = 5 dispensers; Tolerance 100+/-2 pieces

Product Specification

This product is Class I category device as defined by the FDA in 21CFR Parts 807 sub parts C

Material

Nitrile Butadiene Rubber

BSE/TSE Statement

N/A

Non-Pyrogenic Statement

N/A

Dnase & RNase Free Statement:

N/A

Cytotoxicity Statement

N/A

Latex Statement

This product is not made with natural rubber latex

Signed:

PT. SMART GLOVE INDONESIA

JL PELITA RAYA NO 5-7, KAWASAN INDUSTRI MEDAN STAN JL RAYA MEDAN-LUPUK PAKAM KM 19, TANJUNG MORAWA B TANJUNG MORAWA, DELI SERDANG, KODE POS 20362 SUMATERA UTARA, INDONESIA.
Poppy Farahrosa

QA/RA .Manager



COQ Ref No: PTSG-IND0671

CERTIFICATE OF QUALITY

Product Name

9" (4 mil) Powder Free Nitrile Textured Examination Glove Blue

Description Catalog No

9" (4 mil) Powder Free Nitrile Textured Examination Glove Blue

82026-424

Lot Number

PT18L305

Date Of Manufactur

September 2018

Product Shelf Life

Agustus 2023

Country Of Origin

INDONESIA

Quality System Compliance:

Products are manufactured under FDA510K, ISO 9001:2008, ISO 13485:2003I, CMDCAS Quality System standard and Good Manufacturing Practices. Products are Inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP. Inspection records are reviewed and signed off by qualified

personnel for product release.

QC Testing

Representative production samples are collected and inspected in

Accordance with current applicable product specification: Meet or exceed ASTM D6319 and ISO 2859 (Sampling table)

Accuracy

Water tight test

Inspection level = G1; AQL 1.5

Visual inspection

Inspection level = G1; AQL 1.5 (critical defects)

AQL 2.5 (major defects) AQL 4.0 (minor defects)

Dimensional

Inspection level = S2; AQL 4.0

Physical Property

Powder Content

Inspection level = S2; AQL 4.0

Moisture Content

Inspection level = 5pieces; Average ≤ 2 mg/glove

Inspection level = 5pieces; Average ≤ 1%

Glove count

Inspection level = 5 dispensers; Tolerance 100+/-2 pieces

Product Specification

This product is Class I category device as defined by the FDA in 21CFR Parts 807 sub parts C

Material

Nitrile Butadiene Rubber

BSE/ TSE Statement

N/A

Non-Pyrogenic Statement

N/A

Dnase & RNase Free Statement:

N/A

Cytotoxicity Statement

N/A

Latex Statement

This product is not made with natural rubber latex

AT. SMART GLOVE INDONESIA PIL DIMARTI GLUVE INDUNESIA

PELITA RAYA NO 5-7, KAWASAN INDUSTRI MEDAN STAR,

RAYA MEDAN-LUPUK PAKAM KM 19, TANJUNG MORAWA B

TANJUNG MERAWA, DELI SERDANG, KODE POS 20362

SUMATERA UTARA, INDONESIA.

Poppy Farahrosa QA/RA .Manager