

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
Physical Property : Inspection level = S2; AQL 4.0
Powder Content : Inspection level = 5pieces; Average \leq 2 mg/glove
Moisture Content : Inspection level = 5pieces; Average \leq 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 STAR,
JL RAYA MEDAN - LUBUK PAKAM KM 19, TANJUNG MORAWA B
TANJUNG MORAWA, DELI SERDANG, KODE POS 20362
SUMATERA UTARA, INDONESIA.

Poppy Farahrosa
QA/RA .Manager

Date : 01 November 2018

COQ 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
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
Physical Property : Inspection level = S2; AQL 4.0
Powder Content : Inspection level = 5pieces; Average \leq 2 mg/glove
Moisture Content : Inspection level = 5pieces; Average \leq 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 STAR,
JL RAYA MEDAN-LUPEK PAKAM KM 19, TANJUNG MORAWA B
TANJUNG MORAWA, DELI SERDANG, KODE POS 20362
SUMATERA UTARA, INDONESIA.

Poppy Farahrosa
QA/RA .Manager

Date : 01 November 2018

COQ Ref No: PTSG-IND0668

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 : 82026-426
Lot Number : PT18N004 & PT18N005
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
Physical Property : Inspection level = S2; AQL 4.0
Powder Content : Inspection level = 5pieces; Average \leq 2 mg/glove
Moisture Content : Inspection level = 5pieces; Average \leq 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 STAR,
JL RAYA MEDAN - LUBUK PAKAM KM 19, TANJUNG MORAWA B
TANJUNG MORAWA, DELI SERDANG, KODE POS 20362
SUMATERA UTARA, INDONESIA.

Poppy Farahrosa
QA/RA .Manager

Date : 01 November 2018

COQ Ref No: PTSG-IND0669

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 : 82026-428
Lot Number : PT18N006 & PT18N007
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
Physical Property : Inspection level = S2; AQL 4.0
Powder Content : Inspection level = 5pieces; Average \leq 2 mg/glove
Moisture Content : Inspection level = 5pieces; Average \leq 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 STAR,
JL RAYA MEDAN-LUBUK PAKAM KM 19, TANJUNG MORAWA B
TANJUNG MORAWA, DELI SERDANG, KODE POS 20362.
SUMATERA UTARA, INDONESIA.

Poppy Farahrosa
QA/RA .Manager

Date : 01 November 2018

COQ 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 : PT18L302 & PT18L303
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 : Inspection level = S2; AQL 4.0
Powder Content : Inspection level = 5pieces; Average \leq 2 mg/glove
Moisture Content : Inspection level = 5pieces; Average \leq 1%
Glove count : Inspection level = 5 dispensers; Tolerance 100+/-2 pieces

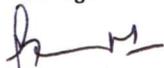
Product Specification : This product is Class I category device as defined by the FDA in 21CFR Parts 807 sub parts C

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 STAR,
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



Date : 01 November 2018

COQ Ref No: PTSG-IND0671

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 : 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 : Inspection level = S2; AQL 4.0
Powder Content : Inspection level = 5pieces; Average \leq 2 mg/glove
Moisture Content : Inspection level = 5pieces; Average \leq 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 STAR,
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

Date : 01 November 2018