CERTIFICATE NO. : 17480

COMFORT RUBBER GLOVES INDUSTRIES SDN. BHD.

CERTIFICATE OF RELEASE - ASTM

NAME OF CUSTOMER : KKG PROTECT SDN BHD

CUSTOMER P. O. NO. : 20113

BRAND : NITRI ONE NITRILE GLOVE

PRODUCT DESCRIPTION : Non-Sterile Nitrile Examination Gloves
MIN. 240MM POWDER FREE CHLORINATED FINGER TEXTURED, BLUE

The above shipment has been inspected and verified to comply with ASTM D3578 / ASTM D6319 STANDARD.

Size	XS	S	M	L	XL	XXL	
Packing Lot No.	-	012DD170	012DD171	-	-	-	TOTAL
Quantity (No of) in Dispenser	-	1,000,000	2,400,000	-	-	-	3,400,000
Quantity (No of) in Carton	-	1,000	2,400	-	-	-	3,400

* The detail results of the above inspection is contained in the following pages.

Approved & Authorized for Release by :

Q.A MANAGER / ~~EXEC~~.

Date : 10.12.2020

(A) QA INSPECTION RESULT

Inspection Based on: [ ] ASTM D3578 [X] ASTM D6319

1.0 WATER TIGHT TEST (With 1000mL water, Inspection / AQL Level: G1 / AQL - 0.65 / 1.0 / 1.5 / 2.5 / 4.0 / 6.5)

Size	XS	S	M	L	XL	XXL	TOTAL SAMPLE	DISPOSITION
Sample Size	-	147	353	-	-	-	500	
Acceptance Level	-	-	-	-	-	-	A-14 R-15	[X] PASS
Pinhole Palm		0	3					
Pinhole Crotch		1	3					[ ] FAIL
Total Defects	0	1	6	0	0	0	7	
						RESULT	PASS	

2.0 VISUAL INSPECTION (Inspection / AQL Level: G1 / AQL- 0 (Critical), 2.5 (Major), 4.0 (Minor))

Size	XS	S	M	L	XL	XXL	TOTAL SAMPLE	DISPOSITION
2.1 Critical Defects								
Sample Size	-	147	353	-	-	-	500	[X] PASS
Acceptance Level	-	-	-	-	-	-	A-0 R-1	[ ] FAIL
Total Defects	0	0	0	0	0	0	0	
						RESULT	PASS	
2.2 Major Defects								
Sample Size	-	147	353	-	-	-	500	[X] PASS
Acceptance Level	-	-	-	-	-	-	A-21 R-22	
Dirt > 0.5mm2		0	1					[ ] FAIL
Stain > 0.5mm2		2	3					
Defective Bead		1	2					
Rolled Cuff		0	4					
Thin Spot / Thin Layer		0	1					
Total Defects	0	3	11	0	0	0	14	
						RESULT	PASS	
2.3 Minor Defects								
Sample Size	-	93	222	-	-	-	315	[X] PASS
Acceptance Level	-	-	-	-	-	-	A-21 R-22	
Lump < 2mm2		0	3					[ ] FAIL
Dirt < 0.5mm2		1	2					
Stain < 0.5mm2		1	1					
Total Defects	0	2	6	0	0	0	8	
						RESULT	PASS	

3.0 COUNT GLOVES (Inspection / AQL Level: S2 / AQL4.0) - Tolerance ± 2 Sample Size , n = 13 Accept-1, Reject-2

Size // n	1	2	3	4	5	6	7	8	9	10	11	12	13	RESULT
XS	-	-	-	-	-	-	-	-	-	-	-	-	-	-
S	101	99	101	102	100	100	101	101	100	100	101	99	100	PASS
M	100	101	100	100	101	100	100	101	101	101	101	101	99	PASS
L	-	-	-	-	-	-	-	-	-	-	-	-	-	-
XL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
XXL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DISPOSITION :		X	PASS			FAIL								

4.0 DIMENSION (Inspection / AQL Level: S2 / AQL 4.0) Sample Size , n = 13 pcs/ size Accept-1, Reject-2

Parameter	Width (mm)	Length (mm)	Cuff	Palm	Finger	Beading Diameter	DISPOSITION
Size/ Spec	(S:85/M:95/L:105/XL:115) ±5mm / XXL: >120mm	Min 240	0.07 ± 0.01mm	0.10 ± 0.02mm	0.12 ± 0.02mm	0.8 To 3.0mm	
XS	-	-	-	-	-	-	X PASS
S	87 TO 88	246 TO 250	0.07 TO 0.08	0.09 TO 0.11	0.12 TO 0.14	0.8	
M	97 TO 98	244 TO 247	0.06 TO 0.08	0.08 TO 0.09	0.11 TO 0.13	0.8 TO 1.0	
L	-	-	-	-	-	-	FAIL
XL	-	-	-	-	-	-	
XXL	-	-	-	-	-	-	

(B) PHYSICAL PROPERTIES (Inspection / AQL Level: S2 / AQL 4.0)

(ASTM-S2: AQL 4.0)

	Sample (n)	1	2	3	4	5	6	7	8	9	10	11	12	13
Before Ageing	Tensile Strength	21.0	20.6	21.7	20.7	21.4	21.0	22.3	21.1	21.7	21.8	21.5	21.3	18.3
	Elongation	652	650	600	594	648	632	564	538	621	610	574	551	650
After Ageing	Tensile Strength	18.5	21.7	22.5	17.8	19.7	19.5	19.8	18.9	20.9	22.3	19.9	19.7	18.3
	Elongation	496	576	654	584	515	538	610	525	628	574	529	571	581

Specification :	Tensile Strength	Elongation	Accept	Reject	DISPOSITION :
Before Ageing	Min 14MPa	Min 500%	1	2	[X] PASS [ ] FAIL
After Ageing	Min 14MPa	Min 400%	1	2	

(C) POWDER CONTENT (Inspection / AQL Level : G1 / AQL 0)

Powder(mg) // Size	XS	S	M	L	XL	XXL	DISPOSITION
Powdered : n = 2 pcs per size Spec : Max 10.00mg/dm^2 Powder free : n = 5 pcs per size Spec : Max 2.00 mg/ glove Accept - 0, Reject - 1	-	0.40	0.44	-	-	-	[X] PASS [ ] FAIL

(D) PROTEIN CONTENT (Inspection / AQL Level: G1 / AQL 0)

Protein (µg/dm^2) // Size	XS	S	M	L	XL	XXL	DISPOSITION
Sample Size , n = 3 pcs per size (ASTM) Powdered : Max 200µg/dm^2 Powder free : Max 50 µg/ dm^2 Accept - 0, Reject - 1		NOT APPLICABLE FOR NITRILE GLOVES					[ ] PASS [ ] FAIL

*Based on the review of the above data, we certify that the gloves inspected have passed ASTM Standard : D3578 / D6319 with regards to water tight, dimension and Comfort Rubber visual standard.

Certificate MY09/77229

The management system of

Comfort Rubber Gloves Industries Sdn. Bhd.

Lot 821 & 2209, Jalan Matang
34750 Matang, Taiping, Perak Darul Ridzuan
MALAYSIA

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 07 April 2018 until 06 April 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 07 February 2021
Issue 6. Certified since 07 April 2009

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

Comfort Rubber Gloves Industries Sdn. Bhd.

ISO 13485:2016
EN ISO 13485:2016

Issue 6

Detailed scope

Manufacture of Non-Sterile Powdered & Powder Free Natural Latex & Nitrile Examination Gloves

Additional facilities

Lot 1874, Jalan Kampung Dew
34700 Taiping, Perak Darul Ridzuan
MALAYSIA

UKAS MANAGEMENT SYSTEMS
0005

Issued to:

Comfort Rubber Gloves Industries Sdn.Bhd
Lot 821
34750 Matang
Jalang Matang
Perak
Malaysia

Notified Body: 2777

SATRA customer number: P1898

EU Type-Examination Certificate

Certificate number: 2777/12061-01/E00-00

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: PFNBR243

Description: Powder free Nitrile examination gloves

Sizes: 7 – 11

Classification:

EN ISO 374-1:2016/Type C	**Level**	**EN 374-4:2013 Degradation %**
40% Sodium hydroxide	6	-14.0
37% Formaldehyde	5	20.5

EN ISO 374-5:2016	
Protection against bacteria and fungi	Pass
Protection against viruses	N/A

Standards/Technical specifications applied:
EN 420: 2003+A1: 2009; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: SPC0271175/1821/2, CHM0271163/1821/JS/G, CHM0271163/1821/JS/F

Signed on behalf of SATRA:

Mohammed Rahman

Austin Simmons

Date first issued: 26/02/2019
Date of issue: 26/02/2019

Expiry date: 26/02/2024

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity. Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the certification and product are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
8. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
9. SATRA Technology reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 2009

Comfort Rubber Gloves IND. SDN. BHD.
Mr. Tan K. Beng
Managing Director
Lot 821, Jalan Matang, 34750 Matang
Taiping, Perak
MALAYSIA

Re: K083624
Trade/Device Name: Powder Free Nitrite (Blue and White) Examination Gloves
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: January 19, 2009
Received: January 26, 2009

Dear Mr. Beng.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for
Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant : Comfort Rubber Gloves Ind. Sdn. Bhd.

510(k) Number (if known): K083624

Device Name: POWDER FREE NITRILE (BLUE AND WHITE) EXAMINATION GLOVES.

Indications for Use:

A powder-free patient examination glove is a disposable device made of synthetic material that is intended for medical purposes to be worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A Murphy MD

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083624

Comfort Rubber Gloves Industries S/B

TENSILE STRENGTH TEST RESULT (ASTM 6319)

(UNAGED)

Type of glove: OCF40NBBL
Lot No. : 00108F210-10
Off Line Lot No.:
Size:M-240mm
Sample: ONLINE
Tensile Machine Id : P499-M
Ruler Id : P662-M
Oven Id : -
Die Cutter Id : P567-M
Tested date: 11-05-2020

Tensile Strength:-
Unaged:- Min 14 Mpa
Ultimate Elongation :-
Unaged:- Min 500%

Test No.	Weight g	Width mm	Area mm^2	FAB N	T.Strength MPa	Elongation %	M@300% MPa	M@500% MPa	M@700% MPa
1	3.890	6	0.36	9.91	27.54	659	5.397	11.580	-
2	3.818	6	0.36	9.63	26.74	663	5.373	11.577	-
3	3.827	6	0.36	11.48	31.88	621	5.519	13.586	-
4	3.898	6	0.36	9.20	25.57	632	5.494	11.959	-
5	3.836	6	0.36	8.95	24.87	663	4.929	10.274	-
6	3.814	6	0.36	10.11	28.09	663	5.021	10.793	-
7	3.806	6	0.36	9.49	26.37	594	5.717	14.751	-
8	3.811	6	0.36	11.51	31.96	611	5.495	14.548	-
9	3.778	6	0.36	9.78	27.18	650	5.738	14.280	-
10	3.846	6	0.36	10.41	28.93	680	5.236	11.920	-
11	3.855	6	0.36	9.31	25.86	629	5.123	11.659	-
12	3.806	6	0.36	8.27	22.97	594	5.280	12.709	-
13	3.731	6	0.36	9.15	25.41	609	5.569	13.558	-
Average	3.824	6	0.36	9.78	27.18	636	5.376	12.553	0.000
$SD^{(N-1)}$	0.044	0	0.00	0.93	2.59	29	0.250	1.462	0.000
Medium	3.818	6	0.36	9.63	26.74	632	5.397	11.959	0.000
Maximum	3.898	6	0.36	11.51	31.96	680	5.738	14.751	0.000
Minimum	3.731	6	0.36	8.27	22.97	594	4.929	10.274	0.000

Tested by: AIN ISHAK
(Lab Assistant and above)

Verified by: Nora.
(Lab Sr. Supervisor and above)

Comfort Rubber Gloves Industries S/B

TENSILE STRENGTH TEST RESULT (ASTM STD)

(AGED)

Type of glove: OCF40NBBL
Lot No.: 00108F210-10
Off Line Lot No.:
Size: M-240mm
Sample: ONLINE
Tensile Machine Id : P499-M
Ruler Id : P804-M
Oven Id : P191-M
Die Cutter Id : P560-M
Tested date: 18-05-2020

Tensile Strength:-
Aged:- Min 14 Mpa
Ultimate Elongation :-
Aged:- Min 400%

Test No.	Weight g	Width mm	Area mm^2	FAB N	T.Strength MPa	Elongation %	M@300% MPa	M@500% MPa	M@700% MPa
1	3.890	6.00	0.36	9.33	25.92	556	6.361	17.958	-
2	3.818	6.00	0.36	8.18	22.72	501	6.972	-	-
3	3.827	6.00	0.36	11.08	30.77	477	8.273	-	-
4	3.898	6.00	0.36	8.50	23.60	490	7.598	-	-
5	3.836	6.00	0.36	8.64	24.01	565	6.328	16.066	-
6	3.814	6.00	0.36	8.02	22.27	541	6.717	17.633	-
7	3.806	6.00	0.36	9.97	27.70	394	12.355	-	-
8	3.811	6.00	0.36	11.03	30.63	486	8.322	-	-
9	3.778	6.00	0.36	9.25	25.69	473	7.227	-	-
10	3.846	6.00	0.36	11.96	33.21	604	5.777	16.155	-
11	3.855	6.00	0.36	10.56	29.35	547	6.760	21.996	-
12	3.806	6.00	0.36	11.43	31.76	591	6.494	17.903	-
13	3.731	6.00	0.36	10.51	29.19	532	6.980	23.625	-
Average	3.824	6.00	0.36	9.88	27.45	520	7.397	18.762	0.000
$SD^{(N-1)}$	0.044	0.00	0.00	1.32	3.66	57	1.662	2.911	0.000
Medium	3.818	6.00	0.36	9.97	27.70	532	6.972	17.903	0.000
Maximum	3.898	6.00	0.36	11.96	33.21	604	12.355	23.625	0.000
Minimum	3.731	6.00	0.36	8.02	22.27	394	5.777	16.066	0.000

Tested by: ILLI NAJWA
(Lab Assistant and above)

Verified by: Nora
(Lab Sr. Supervisor and above)

NitriOne Nitrile Examination Gloves - Box Photo