



## AT UYGUNLUK BİLDİRİMİ EC DECLARATION OF CONFORMITY

Aşağıda belirtilen ürünlerin, 93/42/AT Tıbbi ve 2007/47/AT Cihaz Yönetmeliği gereksinimlerine göre yapıldığını beyan ederiz.

We herewith declare that the following mentioned products meet the provisions the Council Directive 93/42/EEC and 2007/47/EC for Medical Device Directive.

**Üretici:** BEYBİ PLASTİK FABRİKASI SANAYİ A.Ş.  
*Manufacturer*

**Adres:** Yukarı Dudullu Organize Sanayi Bölgesi 1. Cad. No: 27  
*Address* Ümraniye / İSTANBUL / TÜRKİYE

**Ürün:** *Product*

Beybi Ürün Adı / Beybi Product Name	GMDN	Boy /Size	Katalog No/Catalog No
Njoy Pudrasız Nitril Muayene Eldiveni (Mavi) Njoy Powder Free Nitrile Examination Gloves (Blue)	40546	S	23.08002
		M	23.08001
		L	23.08000
		XL	23.08003

**Sınıflandırma** : Sınıf I  
*Classification* Class I

**Uygunluk Değerlendirme Prosedürü:** Ek VII  
*Conformity Assessment Route: Annex VII*

**Yürürlük Tarihi** : 07 January 2019 / 07 January 2019  
*Date of Issue*

**Deniz BOZAR**  
**Kalite Yöneticisi / Quality Manager**  
07 January 2019 / 07 January 2019

  
PLASTİK FAB. SANAYİ A.Ş.  
Y.Dudullu Org. San. Bölge. 1. Cad. No:27 Ümraniye  
Tel: 0.216 420 11 01 (6 Hat) Fax: 0.216 313 55 49  
Anadolu Kurumlar V.D. 1670046198 İSTANBUL

**BEYBİ PLASTİK FAB. SAN. A.Ş**

Organize Sanayi Bölgesi 1. Cadde No: 27 Ümraniye / İstanbul / TÜRKİYE / TURKEY  
Tel: +90 Tel: +90 216 420 11 01 (6 hat / lines) Fax: + 90 216 313 55 49 Web: [www.beybi.com.tr](http://www.beybi.com.tr) e-posta: info@beybi.com.tr

UYGUNLUK BİLDİRİMİ  
DECLARATION OF CONFORMITY

# BEYBİ İŐ GÜVENLİĐİ MALZEMELERİ SANAYİ VE TİCARET ANONİM ŐİRKETİ

Yukarı Dudullu Organize Sanayi Bölgesi 1.Cadde No:27 Ümraniye İSTANBUL / TÜRKİYE

## AT UYGUNLUK BEYANI

Beybi Marka, Pn810 Model

Performans Seviyesi 3131X

Polyester İplikten Dokuma ve Nitril ile Yarı Kaplanmış Mekanik Risklere Karşı Koruyucu Eldiven

Kişisel Koruyucu Donanım 2163 Onaylanmış Kuruluş kimlik numaralı  
Universal Sertifikasyon ve Gözetim Hizmetleri Ticaret Limited Őirketi/ Necip Fazıl Bulvarı Keyap Sitesi  
E2 Blok No:44/84 Yukarı Dudullu Ümraniye/İSTANBUL firması tarafından *TS EN 388:2016 Mekanik  
Risklere Karşı Koruyucu Eldivenler & TS EN 420 +A1:2010 Koruyucu eldivenler-Genel Özellikler ve  
Deney Yöntemleri* standartlarına göre AT Tip İncelemesine tabi tutulmuştur, Kategori II için ilgili  
hükümlerinin şartlarını, Kişisel Koruyucu Donanımın 89/686/EEC Konsey Direktifi hükümlerini ve yerini  
aldığı ulusal harmonize standart olan TS EN 388:2016 & TS EN 420 +A1:2010 hükümlerini karşıladığını  
ve uygunluğunu beyan ederiz.

HAYİM AZOZ  
Genel Müdür

İstanbul 12.06.2018

CE  
2163



# PCA

PARTNERS CERTIFICATE  
ASSURANCE



# Sertifika

## ISO 9001 : 2015

### BEYBİ PLASTİK FABRİKASI SAN. A.Ş.

Y. Dudullu Org. San. Böl. 1. Cd. No:27 Ümraniye-İstanbul/TÜRKİYE

Bu sertifika yukarıdaki kuruluşa alt kalite yönetim sisteminin aşağıdaki kapsam çerçevesinde PCA Sertifikasyon tarafından onaylandığını göstermekte olup, sertifikamın geçerliliği kuruluşun yıllık gözetim denetimlerinden geçmesine ve Uluslararası akreditasyon kuralları gereğince ilgili yönetim sisteminin şartlarını devam ettirmesine bağlıdır.

### KAPSAM

Medikal muayene eldiveni, steril cerrahi eldiven, medikal sarf malzemeleri, ev işleri ve sanayi eldivenlerinin satış ve pazarlaması

**Sertifika No** : KY-26513  
**Tescil Tarihi** : 03.05.2019  
**Yeniden Basım Tarihi** :  
**Geçerlilik Tarihi** : 02.05.2020  
**Belge Periyodu** : 3 Yıl (Tescil Tarihinden itibaren)



TURKAK BDS NO  
YS-EC3B-B7E6



Kalite Yönetim Sistemi  
TS EN ISO/IEC 17021  
AB-0076-YS



PCA Sertifikasyon Onayı

PCA Sertifikasyon Hizmetleri Limited Şirketi  
Atalar Mah. Çanakkale Caddesi No:79 D:3 Kartal / İSTANBUL  
Tel: +90 216 510 63 48-49 Pbx Faks: +90 216 517 63 49  
www.pca-tr.com info@pca-tr.com

FR.B6 Rev.4

Sertifikaların durumu "Kare Kod" mobil cihazlarla okutulurak veya <https://tbds.turkak.org.tr> adresinden TBDS belge no ile sorgulanabilir.



# Sertifika

## ISO 13485:2016

### BEYBİ PLASTİK FABRİKASI SAN. A.Ş. Y. Dudullu Org. San. Böl. 1. Cd. No:27 Ümraniye-İstanbul/TÜRKİYE

Bu sertifika yukarıdaki kuruluşa ait tıbbi cihazlar kalite yönetim sisteminin (EN ISO 13485:2016) aşağıdaki kapsam çerçevesinde PCA Sertifikasyon tarafından onaylandığını göstermekte olup, sertifikanın geçerliliği kuruluşun yıllık gözetti denetimlerinden geçmesine ve uluslararası akreditasyon kuralları gereğince ilgili yönetim sisteminin şartlarını devam ettirmesine bağlıdır.

### KAPSAM

Muayene eldiveni ürettirilmesi, medikal sarf malzemelerinin alımı, satışı, depolanması ve dağıtımı

#### GRUP KODU

M01-MDS7006

<b>Sertifika No</b>	: TC-75051
<b>Tescil Tarihi</b>	: 12.04.2018
<b>Yeniden Basım Tarihi</b>	: 03.05.2019
<b>Geçerlilik Tarihi</b>	: 11.04.2020
<b>Belge Periyodu</b>	: 3 Yıl (Tescil Tarihinden İtibaren)
<b>Hariç Tutma</b>	: 7.3 /7.5.1/7.5.2/7.5.3/7.5.4/7.5.5 7.5.6/ 7.5.7/7.5.9.2



#### PCA Sertifikasyon Onayı

PCA Sertifikasyon Hizmetleri Limited Şirketi  
Atalar Mah. Çanakkale Caddesi No:79 D:3 Kartal / İSTANBUL  
Tel: +90 216 510 63 48-49 Pbx Faks: +90 216 517 63 49  
www.pca-tr.com info@pca-tr.com





## CERTIFICATE

### BEYBİ PLASTİK FABRİKASI SAN. A.Ş.

Yukarı Dudullu Org. San. Böl. 1. Cadde No:27 Dudullu / İSTANBUL

DSR BELGELENDİRME tarafından denetlenmiş ve uygulamakta olduğu  
Bilgi Güvenliği Yönetim Sisteminin

*is audited by DSR Certification and applied  
Information Security Management System meet the requirements of*

# ISO 27001:2013

standardına aşağıdaki kapsamda uymakta olduğu gözlenmiştir.  
*standard for the following activities.*

STERİL CERRAHİ ELDİVENLER, MEDİKAL SARF MALZEMELER, MUAYENE ELDİVENLERİ, EV İŞLERİ  
ELDİVENLERİ GÜMRÜK VE DIŞ TİCARET İŞLEMLERİNİ VE BU İŞLEMLERİNE İLİŞKİN LOJİSTİK, DEPOLAMA,  
MUHASEBE, FİNANS VE BİLGİ İŞLEM FAALİYETLERİNİN BİLGİ VARLIKLARI İLE BU VARLIKLARI KORUMAK

**Sertifika No / Certificate No: ISMS-18.03.206**

23.05.2018

Sertifika Tarihi  
Certificate Date

23.05.2018

Sertifika Son Basım Tarihi  
Certificate Last Issue Date

22.05.2021

Belgelendirme Periyodu Bitiş  
Tarihi  
Certification Period Expiration Date

22.05.2019

Sertifika Geçerlilik Tarihi  
Certificate Expiry Date

SoA: 19.03.2018 Rev.00



TÜRKAK BDS NO  
YS-B1D6-6710



Rev.00 / Revizyon Tarihi:

FR-072 Yayın Tarihi:18.04.2017 Rev.No:00 Rev.Tarihi:

**DSR ULUSLARARASI GÖZETİM VE BELGELENDİRME HİZMETLERİ LTD. ŞTİ.**

Yeşilbağlar Mah. Eğitim Sk. No: 43 Daire: 2 Tel: +90 216 606 06 35 PENDİK / İSTANBUL / TÜRKİYE  
E-mail: info@dsrgozetim.com - Web: www.dsrgozetim.com



# EC TYPE-EXAMINATION CERTIFICATE

**Certificate Number: 2163 - PPE - 906**

Personnel Protective Equipment - Protective Gloves Against Mechanical Risks  
produced by

**BEYBİ İŞ GÜVENLİĞİ MALZEMELERİ SANAYİ VE TİCARET  
ANONİM ŞİRKETİ**

**Yukarı Dudullu Organize Sanayi Bölgesi 1.Cadde No:27 Umraniye İSTANBUL / TURKEY**  
has been subject to an EC Type-examination in accordance with

**EN 388:2016 & EN 420:2003+A1:2009**

and has been shown to satisfy the relevant provisions of Personnel Protective Equipments Directive  
(89/686/EEC) Category II

## Product Description

Beybi Brand, Pn810 Model

Performance Level 3131X

Protective Gloves Against Mechanical Risks Made of Spun Thread Woven and Semi-Coated with  
Nitrile

Conformity with the basic requirements is shown at the KKD-2163-919 numbered technical evaluation  
report. Accordingly, the organization mentioned in this certificate are listed in the above product / products,  
an EC declaration of conformity edit Directive (89/686/EEC) as a mended in compliance with the relevant  
approved type, as follows: CE Conformity Mark on products to attach license are provided.  
This certificate is Directive 89/686/EEC and / or directive provisions connected with the essential health and  
safety requirements of the relevant harmonized standards, unless there is a change affecting valid for 5 years.

**CE**  
2163

in İSTANBUL - 12/06/2018



**Figen BİGÜN**  
UNIVERSAL CERTIFICATION  
Vice General Manager

  
**UNIVERSAL**  
CERTIFICATION

**NB 2163**

UNIVERSAL





**MAXTER**

GLOVE MANUFACTURING SDN BHD  
(229562-H)

**LOT 6070**

Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru  
41050 Klang, Selangor, Malaysia  
Tel: 603-33929888 (8 lines) Fax: 603-33923328  
E-MAIL: info@maxter.com.my

**CERTIFICATE OF ANALYSIS**

LABEL : BEYBI  
 ORDER REF. : G/87853  
 TYPE OF GLOVE : Non Sterile Regular Blue Powder Free Nitrile Examination Glove  
 ANALYSIS DATE : 06/05/2019  
 REFERENCE STANDARD : ASTM D6319

Size	Quantity (Cartons)	Quantity (Pieces)	Lot No.
S	290	580,000	G87853
M	920	1,840,000	G87853
L	1,210	2,420,000	G87853
Total	2,420	4,840,000	

**1. WATERTIGHT TEST**

Inspection level: G1  
 AQL: 1.5

Size	Sample size (pcs)	Acceptance (pcs)	Defects(pcs)	Result
S	500	14	7	Pass
M	500	14	8	Pass
L	500	14	8	Pass

**2. DIMENSIONS**

Inspection level: S2  
 Acceptance: 1  
 AQL: 4.0  
 Defects found: 0  
 Result: Pass

Sample No.	Size	Length (mm)	Width (mm)	Thickness (single wall) (mm)	
				Fingertip	Palm
1	S	245	85	0.12	0.06
2	S	244	85	0.11	0.05
3	M	245	95	0.11	0.06
4	M	244	96	0.10	0.05
5	M	245	95	0.10	0.05
6	M	245	96	0.11	0.05
7	M	246	96	0.11	0.06
8	L	245	104	0.11	0.06
9	L	246	105	0.10	0.05
10	L	244	104	0.11	0.05
11	L	245	104	0.11	0.06
12	L	246	105	0.11	0.05
13	L	244	104	0.10	0.06





**MAXTER**  
 GLOVE MANUFACTURING SDN BHD  
 (229862-H)

**LOT 6070**  
 Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru  
 41050 Klang, Selangor, Malaysia  
 Tel: 603-33929888 (8 lines) Fax: 603-33923328  
 E-MAIL: info@maxter.com.my

**CERTIFICATE OF ANALYSIS**

3. TENSILE STRENGTH & ELONGATION AT BREAK BEFORE ACCELERATED AGEING AND AFTER ACCELERATED AGEING  
 Inspection level: S2  
 AQL: 4.0  
 Acceptance: 1  
 Defects found: 0  
 Result: Pass

Sample No.	Size	Tensile Strength at break before aging (Min 14 MPa)	Elongation before accelerated aging (MIN 500%)	Tensile Strength at break after aging (Min 14 MPa)	Elongation after accelerated aging (MIN 400%)
1	S	22.63	565	19.74	505
2	S	22.18	550	19.27	520
3	M	22.84	560	19.95	510
4	M	23.39	570	20.30	515
5	M	22.32	555	19.41	500
6	M	23.09	550	20.17	505
7	M	22.59	565	19.62	510
8	L	22.74	550	19.82	500
9	L	23.24	570	20.28	515
10	L	22.05	560	19.16	520
11	L	22.93	555	20.00	500
12	L	22.25	570	19.39	515
13	L	22.49	565	19.50	505

4. PROTEIN CONTENT TEST

Size	Protein Content (Max 50µg/dm <sup>2</sup> )	Result
S	N/A	N/A
M	N/A	N/A
L	N/A	N/A


5. POWDER TEST

Size	Powder Content (Max 2mg/glove)	Result
S	0.14	Pass
M	0.18	Pass
L	0.16	Pass

**CONCLUSION:** The lots tested are complied with ASTM D6319 standard as referring to the above findings of randomly selected samples.

PREPARED BY:

*Tracy Chia*  
 Tracy Chia  
 QA CHEMIST



APPROVED BY:

*Rosnita Abdul Hadi*  
 Rosnita Abdul Hadi  
 QA ASSISTANT MANAGER







**MAXTER**

GLOVE MANUFACTURING SDN BHD  
(229862-H)

**LOT 6070**

Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru  
41050 Klang, Selangor, Malaysia  
Tel: 603-33929888 (8 lines) Fax: 603-33923328  
E-MAIL: info@maxter.com.my

**CERTIFICATE OF ANALYSIS**

LABEL : BEYBI  
 ORDER REF. : G/87855  
 TYPE OF GLOVE : Non Sterile Regular Blue Powder Free Nitrile Examination Glove  
 ANALYSIS DATE : 11/05/2019  
 REFERENCE STANDARD : ASTM D6319

Size	Quantity (Cartons)	Quantity (Pieces)	Lot No.
S	290	580,000	G87855
M	920	1,840,000	G87855
L	1,210	2,420,000	G87855
Total	2,420	4,840,000	

1. WATERTIGHT TEST  
 Inspection level: G1  
 AQL: 1.5

Size	Sample size (pcs)	Acceptance (pcs)	Defects(pcs)	Result
S	500	14	7	Pass
M	500	14	8	Pass
L	500	14	7	Pass

2. DIMENSIONS  
 Inspection level: S2  
 Acceptance: 1  
 AQL: 4.0  
 Defects found: 0  
 Result: Pass

Sample No.	Size	Length (mm)	Width (mm)	Thickness (single wall) (mm)	
				Fingertip	Palm
1	S	246	85	0.11	0.05
2	S	244	86	0.11	0.05
3	M	246	95	0.10	0.06
4	M	244	95	0.11	0.05
5	M	247	94	0.11	0.06
6	M	245	95	0.12	0.05
7	M	244	95	0.11	0.05
8	L	245	105	0.10	0.06
9	L	245	105	0.10	0.05
10	L	245	104	0.11	0.06
11	L	246	105	0.11	0.05
12	L	245	105	0.10	0.06
13	L	245	104	0.11	0.05





# MAXTER

GLOVE MANUFACTURING SDN BHD  
(229802-H)

LOT 6070

Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru  
41050 Klang, Selangor, Malaysia  
Tel: 603-33929888 (8 lines) Fax: 603-33923328  
E-MAIL: info@maxter.com.my

## CERTIFICATE OF ANALYSIS

### 3. TENSILE STRENGTH & ELONGATION AT BREAK BEFORE ACCELERATED AGEING AND AFTER ACCELERATED AGEING

Inspection level: S2  
AQL: 4.0  
Acceptance: 1  
Defects found: 0  
Result: Pass

Sample No.	Size	Tensile Strength at break before aging (Min 14 MPa)	Elongation before accelerated aging (MIN 500%)	Tensile Strength at break after aging (Min 14 MPa)	Elongation after accelerated aging (MIN 400%)
1	S	22.56	565	19.62	505
2	S	22.90	570	20.00	520
3	M	22.16	550	19.20	515
4	M	23.17	565	20.23	500
5	M	22.36	550	19.41	510
6	M	22.73	560	19.75	515
7	M	23.39	550	20.41	520
8	L	22.28	570	19.33	505
9	L	23.02	565	20.12	500
10	L	22.82	550	19.89	520
11	L	22.29	560	20.39	500
12	L	22.06	555	19.18	510
13	L	22.41	570	19.52	515

### 4. PROTEIN CONTENT TEST

Size	Protein Content (Max 50µg/dm <sup>2</sup> )	Result
S	N/A	N/A
M	N/A	N/A
L	N/A	N/A

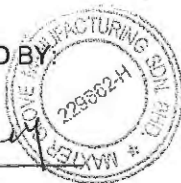
### 5. POWDER TEST

Size	Powder Content (Max 2mg/glove)	Result
S	0.14	Pass
M	0.18	Pass
L	0.16	Pass

CONCLUSION: The lots tested are complied with ASTM D6319 standard as referring to the above findings of randomly selected samples.

PREPARED BY

Tracy Chia  
QA CHEMIST



APPROVED BY

Rosnita Abdul Hadi  
QA ASSISTANT MANAGER







**MAXTER**  
 GLOVE MANUFACTURING SDN BHD  
 (229862-H)

**LOT 6070**  
 Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru  
 41050 Klang, Selangor, Malaysia  
 Tel: 603-33929888 (8 lines) Fax: 603-33923328  
 E-MAIL: info@maxter.com.my

**CERTIFICATE OF ANALYSIS**

LABEL : BEYBI  
 ORDER REF. : G/87856  
 TYPE OF GLOVE : Non Sterile Regular Blue Powder Free Nitrile Examination Glove  
 ANALYSIS DATE : 20/05/2019  
 REFERENCE STANDARD : ASTM D6319

Size	Quantity (Cartons)	Quantity (Pieces)	Lot No.
S	290	580,000	G87856
M	920	1,840,000	G87856
L	1,210	2,420,000	G87856
Total	2,420	4,840,000	

**1. WATERTIGHT TEST**  
 Inspection level: G1  
 AQL: 1.5

Size	Sample size (pcs)	Acceptance (pcs)	Defects(pcs)	Result
S	500	14	8	Pass
M	500	14	7	Pass
L	500	14	8	Pass

**2. DIMENSIONS**  
 Inspection level: S2  
 Acceptance: 1  
 AQL: 4.0  
 Defects found: 0  
 Result: Pass

Sample No.	Size	Length (mm)	Width (mm)	Thickness (single wall) (mm)	
				Fingertip	Palm
1	S	246	85	0.11	0.05
2	S	247	85	0.10	0.05
3	M	245	94	0.11	0.06
4	M	245	95	0.11	0.05
5	M	246	94	0.12	0.06
6	M	245	94	0.11	0.05
7	M	245	95	0.11	0.06
8	L	244	104	0.10	0.06
9	L	245	105	0.11	0.06
10	L	245	105	0.12	0.06
11	L	244	104	0.11	0.06
12	L	247	105	0.11	0.06
13	L	245	105	0.11	0.06





**M A X T E R**  
 GLOVE MANUFACTURING SDN BHD  
 (229862-H)

**LOT 6070**  
 Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru  
 41050 Klang, Selangor, Malaysia  
 Tel: 603-33929888 (8 lines) Fax: 603-33923328  
 E-MAIL: info@maxter.com.my

**CERTIFICATE OF ANALYSIS**

3. TENSILE STRENGTH & ELONGATION AT BREAK BEFORE ACCELERATED AGEING AND AFTER ACCELERATED AGEING  
 Inspection level: S2  
 AQL: 4.0  
 Acceptance: 1  
 Defects found: 0  
 Result: Pass

Sample No.	Size	Tensile Strength at break before aging (Min 14 MPa)	Elongation before accelerated aging (MIN 500%)	Tensile Strength at break after aging (Min 14 MPa)	Elongation after accelerated aging (MIN 400%)
1	S	22.61	565	19.51	505
2	S	22.23	555	19.17	510
3	M	22.81	550	19.71	520
4	M	23.22	570	20.18	515
5	M	22.43	560	19.38	505
6	M	23.06	555	19.94	500
7	M	22.59	565	19.44	510
8	L	22.74	570	19.63	515
9	L	23.39	555	20.33	500
10	L	22.10	560	19.06	515
11	L	23.19	555	20.09	520
12	L	22.93	570	19.89	515
13	L	22.30	560	19.26	500

4. PROTEIN CONTENT TEST

Size	Protein Content (Max 50µg/dm <sup>2</sup> )	Result
S	N/A	N/A
M	N/A	N/A
L	N/A	N/A

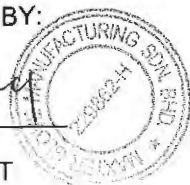
5. POWDER TEST

Size	Powder Content (Max 2mg/glove)	Result
S	0.20	Pass
M	0.16	Pass
L	0.14	Pass

CONCLUSION: The lots tested are complied with ASTM D6319 standard as referring to the above findings of randomly selected samples.

PREPARED BY:

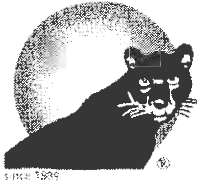
Tracy Chia  
 QA CHEMIST



APPROVED BY:

Rosnita Abdul Hadi  
 QA ASSISTANT MANAGER





**MAXTER**  
GLOVE MANUFACTURING SDN BHD  
(229862-H)

**LOT 6070**  
Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru  
41050 Klang, Selangor, Malaysia  
Tel: 603-33929888 (8 lines) Fax: 603-33923328  
E-MAIL: info@maxter.com.my

### CERTIFICATE OF ANALYSIS

LABEL : BEYBI  
ORDER REF. : G/87857  
TYPE OF GLOVE : Non Sterile Regular Blue Powder Free Nitrile Examination Glove  
ANALYSIS DATE : 22/05/2019  
REFERENCE STANDARD : ASTM D6319

Size	Quantity (Cartons)	Quantity (Pieces)	Lot No.
S	292	584,000	G87857
M	918	1,836,000	G87857
L	1,113	2,226,000	G87857
XL	97	194,000	G87857
Total	2,420	4,840,000	

1. **WATERTIGHT TEST**  
Inspection level: GI  
AQL: 1.5

Size	Sample size (pcs)	Acceptance (pcs)	Defects(pcs)	Result
S	500	14	8	Pass
M	500	14	6	Pass
L	500	14	8	Pass
XL	315	10	4	Pass

2. **DIMENSIONS**  
Inspection level: S2  
Acceptance: 1  
AQL: 4.0  
Defects found: 0  
Result: Pass

Sample No.	Size	Length (mm)	Width (mm)	Thickness (single wall) (mm)	
				Fingertip	Palm
1	S	245	86	0.12	0.05
2	M	246	95	0.11	0.05
3	M	246	95	0.12	0.06
4	M	245	96	0.11	0.05
5	M	244	94	0.11	0.05
6	L	245	104	0.10	0.06
7	L	245	104	0.11	0.05
8	L	245	105	0.11	0.05
9	L	246	106	0.11	0.06
10	L	245	105	0.10	0.05
11	L	244	104	0.11	0.05
12	L	244	105	0.11	0.06
13	XL	246	114	0.10	0.05






**MAXTER**  
 GLOVE MANUFACTURING SDN BHD  
 (229862-H)

**LOT 6070**  
 Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru  
 41050 Klang, Selangor, Malaysia  
 Tel: 603-33929888 (8 lines) Fax: 603-33923328  
 E-MAIL: info@maxter.com.my

**CERTIFICATE OF ANALYSIS**

**3. TENSILE STRENGTH & ELONGATION AT BREAK BEFORE ACCELERATED AGEING AND AFTER ACCELERATED AGEING**

Inspection level: S2  
 AQL: 4.0  
 Acceptance: 1  
 Defects found: 0  
 Result: Pass

Sample No.	Size	Tensile Strength at break before aging (Min 14 MPa)	Elongation before accelerated aging (MIN 500%)	Tensile Strength at break after aging (Min 14 MPa)	Elongation after accelerated aging (MIN 400%)
1	S	22.39	560	19.43	505
2	M	22.06	555	19.10	520
3	M	22.89	550	19.94	510
4	M	22.51	565	19.62	500
5	M	23.18	570	20.28	515
6	L	22.26	550	19.31	500
7	L	22.91	555	20.06	515
8	L	23.24	560	20.36	520
9	L	22.78	555	19.80	500
10	L	22.18	570	19.20	505
11	L	23.09	555	20.17	515
12	L	22.49	560	19.52	500
13	XL	22.69	565	19.74	5200

**4. PROTEIN CONTENT TEST**

Size	Protein Content (Max 50µg/dm <sup>2</sup> )	Result
S	N/A	N/A
M	N/A	N/A
L	N/A	N/A
XL	N/A	N/A

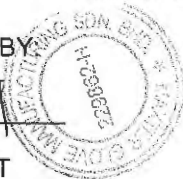
**5. POWDER TEST**

Size	Powder Content (Max 2mg/glove)	Result
S	0.18	Pass
M	0.14	Pass
L	0.20	Pass
XL	0.14	Pass

**CONCLUSION:** The lots tested are complied with ASTM D6319 standard as referring to the above findings of randomly selected samples.

PREPARED BY:

Tracy Chia  
 QA CHEMIST



APPROVED BY:

Rosnita Abdul Hadi  
 QA ASSISTANT MANAGER





**M A X T E R**

GLOVE MANUFACTURING SDN BHD  
(219562-H)

since 1989

**LOT 6070**

Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru  
41050 Klang, Selangor, Malaysia  
Tel: 603-33929888 (8 lines) Fax: 603-33923328  
E-MAIL: info@maxter.com.my

**May 22, 2019**

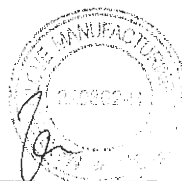
**To Whom It May Concern:**

## **CERTIFICATE OF CONFORMITY**

**We, SUPERMAX GLOVE MANUFACTURING SDN. BHD., located at Lot 38, Putra Industrial Park, Bukit Rahman Putra, 40160 Sungai Buloh, Selangor, Malaysia, declare that the medical devices described hereafter,**

- **“BEYBI” Label, 2.2Mil, 3.0g Regular Blue Colour Powder Free Finger Textured**
  - Small (G87853, G87855, G87856, G87857)**
  - Medium (G87853, G87855, G87856, G87857)**
  - Large (G87853, G87855, G87856, G87857)**
  - X-Large (G87853, G87855, G87856, G87857)**
  
- **Are in conformity with the essential requirements of Medical Device Directive (MDD) 93/42/EEC as amended by Directive 2007/47/EC for Class I non sterile medical devices.**
  
- **The gloves are manufactured according to ISO 9001:2015 and ISO 13485:2016 Quality Management Systems and certified by Notified Body, SGS UK Ltd Systems & Services Certification, Rossmore Business Park Ellesmere Port Cheshire CH653EN UK.**
  
- **Our European Representative is SUPERMAX HEALTHCARE LIMITED., 12-16 Titan Drive, Fengate, Peterborough, PE1 5XN, United Kingdom.**

**Klang, Selangor  
Malaysia**



**Yap Peak Geeh  
QA & Regulatory Affairs Manager**



**Beybi**

PUDRASIZ NİTRİL MUAYENE ELDİVENİ



Serin ve karanlık yerde saklayınız

*This product shall be preserved in cool and dark places*

Steri edilmemiştir  
Non sterile  
EN 455-2

•AQL=1,5

# Beybi®

- İki ele de uyumlu  
*Ambidextrous*
- Tek kullanımlık  
*Single use only*
- Steril değildir  
*Non- Sterile*



**DİKKAT**  
Cerrahi eldiven değildir  
ameliyatlarda kullanılamaz.  
**CAUTION**  
This is not a surgical glove do not use in surgery

CE

**L**  
Büyük/Large

100  
Pcs  
by weight

## Powder-Free Nitrile Examination Gloves





**Beybi**

CAUTION

Powder-Free Nitrile Examination Gloves



CE

L

L

Beybi

L

Beybi

L

Beybi

L

Beybi

L

Beybi

L

Beybi

L

Beybi

L

Beybi

L

Beybi

L

Beybi

L

Beybi

L

L

Beybi

L

Beybi

L

Beybi

L

Beybi

L

Beybi

L

Beybi

L

Beybi

L

Beybi

L



Eldiven numaranızı  
öğrenmek için elinizi ölçün.  
Measure your glove size.

Çok Küçük / X-Small  $\leq 80$  mm

Küçük / Small  $80$  mm  $\pm 10$

Orta / Medium  $90$  mm  $\pm 10$

Büyük / Large  $110$  mm  $\pm 10$

Ekstra Büyük / X-Large  $\geq 110$  mm



**UYARI:**

Hesari ambalajları kullanmayınız. Sert ve karanlık yerde saklayınız.  
Ref ömrü üretim tarihinden sonra 5 yıldır. Ortaya uygundur, asidik  
gıda maddeleri hariç. (40°C de 2 saat test edilmiştir. EU No 10/2011)



**CAUTION:**

Do not use if the package is damaged. Preserve in cool and dark place  
5 years of shelf life after date of production. This product is suitable for  
food handling excluding acidic foodstuffs (tested for 2 hours at 40°C.  
EU No 10/2011)

Ref. No: 23.08000

LOT NO. 231091769NCZB



MADE IN MALAYSIA