



Beybi

- 50 adet 20'lik Ambidextrous
- Tek kullanımlık Single use only
- Steril ambalaj Non-Sterile

Mavi Blue



CE

M
Orta Mediyum

100
GLOVES

Powder-Free Nitrile Examination Gloves

Beybi

PUDRASIZ NİTRİL MUAYENE EL DİVENİ

DIKKAT

CAUTION

This is not a surgical glove do not use in surgery



SUPERMAX
GLOVE MANUFACTURING SDN BHD
(218698-T)

Lot 38, Putra Industrial Park, Bukit Rahman Putra
40160 Sungai Buloh, Selangor Darul Ehsan, Malaysia
Tel: 603-61452328 (30 lines) Fax: 603-61562191 / 61452268
E-MAIL: info@supermax.com.my
www.supergloves.com

4th April 2019

To Whom It May Concern:

DECLARATION OF CONFORMITY

We, SUPERMAX GLOVE MANUFACTURING SDN. BHD. (218698-T), located at Lot 38, Putra Industrial Park, Bukit Rahman Putra, 40160 Sungai Buloh, Selangor, MALAYSIA, declare that the following medical devices manufactured by us as,

Name of Device : Non-Sterile Nitrile Examination Gloves
Type : Powder Free
GMDN : 56286

Brand : **Beybi**[®]
Colour : Black
Thickness/ Weight : 3.2mil at 3.5gm (M size)
Sizes : size S, M, L and XL
Expiry Date : 5 years from date of manufacture
Country of Origin : Malaysia
Conformity Route : Self Declaration

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 medical devices.
- The conformity route of the devices mentioned above is based on Annex VII, Medical Device Directive (MDD) 93/42/EEC as amended by Directive 2007/47/EC.
- 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, located at 12-16 Titan Drive, Fengate, Peterborough, PE1 5XN, United Kingdom.

Sungai Buloh, Selangor
Malaysia



Yap Peak Geeh
QA & Regulatory Affairs Manager



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 (Siyah) Njoy Powder Free Nitrile Examination Gloves (Black)	40546	S	23.08125
		M	23.08126
		L	23.08127
		XL	23.08128

Sınıflandırma : Sınıf I
Classification : *Class I*

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

Yürürlük Tarihi : 05 February 2018 / 05 February 2018
Date of Issue

Deniz BOZAR
Kalite Yöneticisi / Quality Manager
05 February 2018 / 05 February 2018


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

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UYGUNLUK BİLDİRİMİ
DECLARATION OF CONFORMITY