

GOLD DISPOSABLE  
FOR  
MEDICAL SOLUTION

# Den-consultant

MANAGING YOUR SALES

# SAFETY FIRST

Den-consultant Ltd

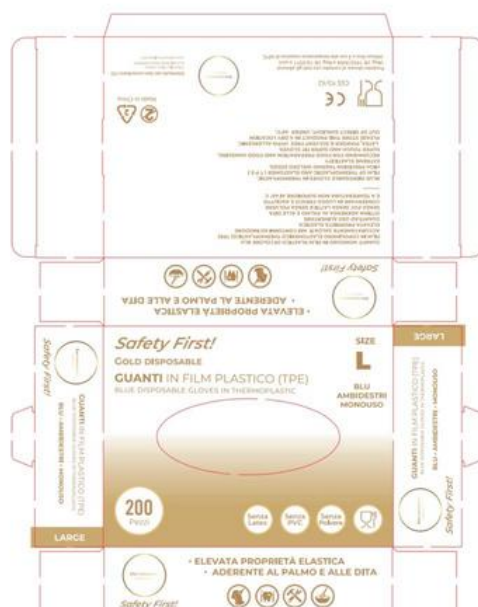
TPE GLOVE

# TPE GLOVE



## Termoplastic Elastomeric Copolymer

DPI Categoria I ambidestro gr2 Blue  
Box da 200 pz Cts da 10box  
Certificato CE  
EN 420:2003+A1:2009 EN 388:2016  
Omologato al contatto con alimenti.



**Den-consultant Ltd**

BizSpace Office 37,CourtWick Ln, Wick,Littlehampton,West Sussex BN 177 TL UK

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# CERTIFICAZIONI



**Den-consultant Ltd**  
Managing your sales

## DICHIARAZIONE DI OMOLOGAZIONE ALL' USO ALIMENTARE

Si dichiara che il prodotto GOLD DISPOSABLE TPE:

in materiale Termoplastico elasticizzato senza polvere, senza Lattice, è certificato secondo la legislazione di riferimento: DPR 777/82 e DM n. 34 del 21/03/1973 e successivi aggiornamenti e modifiche: direttive 82/711/CEE, 85/572/CEE, 93/8/CEE, 97/48/CE, 2002/72/CE; regolamento 1935/2004/CE, regolamento EU 10/2011 in accordo con la normativa di riferimento: UNI EN 1186 1-15:2003.

In base ai test effettuati\* GOLD DISPOSABLE TPE è idoneo al contatto con prodotti alimentari come altresì CERTIFICATO dal laboratorio di analisi INTERNAZIONALE CPST attraverso

il TEST REPORT del 26/aprile/20202 N°C200422036002

In allegato risultati migratori:

### 1. Overall migration

Test Method: To refer to EN 1186-1:2002 & EN 1186-3:2002& EN 1186-14:2002

测试方法: 参照 EN 1186-1:2002 & EN 1186-3:2002 & EN 1186-14:2002

Test Name 测试项目	Test condition 测试条件	Unit 单位	Result 结果	Requirement 要求
Maximum extractable fraction in 3% Acetic Acid 最大提取量(3%乙酸)	70°C, 2h	mg/dm <sup>2</sup>	4.3	10
Maximum extractable fraction in 10% ethanol 最大提取量(10%乙醇)	70°C, 2h	mg/dm <sup>2</sup>	3.5	10
Maximum extractable fraction in olive oil substitute 95% ethanol 最大提取量(橄榄油替代物, 95%乙醇)	60°C, 2h	mg/dm <sup>2</sup>	5.1	10
Maximum extractable fraction in olive oil substitute heptane 最大提取量(橄榄油替代物, 正庚烷)	40°C, 0.5h	mg/dm <sup>2</sup>	6.8	10

Note: mg/dm<sup>2</sup> = milligram per square decimeter

注: mg/dm<sup>2</sup> = 毫克/平方分米

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# TEST REPORT

**CPST** 欧冠检测  
Euronex Products Testing

Test Report  
测试报告

No. C200422036002  
编号: C200422036002

Date: Apr 26, 2020  
日期: 2020年04月26日

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第1页,共6页

Applicant: Zhangjiagang Yingda plastic products factory  
申请公司: 张家港市盈达塑料制品厂

Applicant Address: Building 4, east side of Huada road and north side of Changshan Road, Changjiang village,  
Jingang town, Zhangjiagang City, Jiangsu Province  
申请公司地址: 江苏省张家港市金港镇长江村华达路东侧、长山路北侧4幢

The following samples were submitted and identified on behalf of the clients as  
以下测试之样品是由申请者所提供及确认

Sample Name:	Disposable TPE Gloves
样品名称:	一次性TPE手套
Lot No.:	Poe/TPE
批号:	Poe/TPE
Model:	S, M, L, XL
型号:	S, M, L, XL
CPST Internal Reference No:	C200422036
编号:	C200422036
Date of Sample Received:	Apr 22, 2020
收样日期:	2020年04月22日
Testing Period:	Apr 22, 2020 to Apr 26, 2020
测试周期:	2020年04月22日至2020年04月26日
Test Method:	Please refer to next pages
测试方法:	请参见下一页
Test Result:	Please refer to next pages
测试结果:	请参见下一页

Signed for and on behalf of  
Euronex (Dongguan) Consumer Products Testing Service Co., Ltd



TESTED BY:

REVIEWED BY:

APPROVED BY:

David wan

Sunshine Liu

Will Pan

万大伟, David  
项目负责人

刘小芳, Sunshine  
报告审核员

潘坚定, Will  
技术总监

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# TEST REPORT

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第2页,共6页

CONCLUSION:

结论:

TESTED SAMPLES

测试样品

TEST ITEM

测试项目

RESULT

结果

Disposable TPE Gloves  
一次性TPE手套

Regulation (EC) No 1935/2004, the Commission  
Regulation (EU) No 10/2011 and its amending regulation  
欧盟法规 No 1935/2004, 欧盟委员会法规No 10/2011及其修订法规

1. Overall migration

1. 全面迁移

2. Specific migration for Primary Aromatic Amines

2. 初级芳香胺迁移

PASS

合格

PASS

合格

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Photo of the Submitted Sample

送检样品照片



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Date: Apr 26, 2020  
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### Test Result(s):

测试结果:

Description of Specimen:

Transparent plastic glove

样品描述:

透明塑料手套

### 1. Overall migration

#### 1.全面迁移

Test Method: To refer to EN 1186-1:2002 & EN 1186-3:2002 & EN 1186-14:2002

测试方法: 参照 EN 1186-1:2002 & EN 1186-3:2002 & EN 1186-14:2002

Test Items 测试项目	Test condition 测试条件	Unit 单位	Result 结果	Requirement 要求
Maximum extractable fraction in 3% Acetic Acid 最大提取量(3%乙酸)	70°C, 2h	mg/dm <sup>2</sup>	4.3	10
Maximum extractable fraction in 10% ethanol 最大提取量(10%乙醇)		mg/dm <sup>2</sup>	3.5	10
Maximum extractable fraction in olive oil substitute 95% ethanol 最大提取量(橄榄油替代物, 95%乙醇)	60°C, 2h	mg/dm <sup>2</sup>	5.1	10
Maximum extractable fraction in olive oil substitute Isooctane 最大提取量(橄榄油替代物, 异辛烷)	40°C, 0.5h	mg/dm <sup>2</sup>	6.8	10

Note : mg/dm<sup>2</sup> = milligram per square decimeter

注释: mg/dm<sup>2</sup> = 毫克每平方米

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### 2. Specific migration for Primary Aromatic Amines

#### 2. 初级芳香胺迁移

Test Method: To refer to the EN 13130-1: 2004, the analysis was performed by LC-MS.

测试方法: 参照 EN 13130-1: 2004, 分析仪器为液相色谱-质谱联用仪。

Analyte 被分析物	Test condition 测试条件	Unit 单位	Result 结果	Limit 限值
Primary Aromatic Amines migration 初级芳香胺迁移	70°C, 2h 3% Acetic Acid 70°C, 2h 3%乙酸	mg/kg	<0.01	0.01

Note:

1. mg/kg = milligram per kilogram = ppm  
2. < = less than

备注:

1. mg/kg = 毫克每千克 = ppm  
2. < = 小于

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Primary Aromatic Amines List:  
初级芳香胺列表:

No. 序号	Name 名称	No. 序号	Name 名称
1	4-aminodiphenyl 4-氨基联苯	14	p-cresidine 2-甲氧基-5-甲基苯胺
2	Benzidine 联苯胺	15	4,4'-methylene-bis-(2-chloroaniline) 4,4'-亚甲基-二-(2-氯苯胺)
3	4-chloro-o-toluidine 4-氯邻甲苯胺	16	4,4'-oxydianiline 4,4'-二氨基二苯醚
4	2-naphthylamine 2-萘胺	17	4,4'-thiodianiline 4,4'-二氨基二苯硫醚
5	o-aminoazotoluene 邻氨基偶氮苯甲苯	18	o-toluidine 邻甲苯胺
6	2-amino-4-nitrotoluene 2-氨基-4-硝基甲苯	19	2,4-diaminotoluene 2,4-二氨基甲苯
7	p-chloroaniline 对氯苯胺	20	2,4,5-trimethylaniline 2,4,5-三甲基苯胺
8	2,4-diaminoanisole 2,4-二氨基苯甲醚	21	2-methoxyaniline 邻氨基苯甲醚
9	4,4'-diaminodiphenylmethane 4,4'-二氨基二苯甲烷	22	4-aminoazobenzene 4-阿基苯甲酯
10	3,3'-dichlorobenzidine 3,3'-二氯联苯胺	23	2,4-Xylidine 2,4-二甲基苯胺
11	3,3'-dimethoxybenzidine 3,3'-二甲氧基联苯胺	24	2,6-Xylidine 2,6-二甲基苯胺
12	3,3'-dimethylbenzidine 3,3'-二甲基联苯胺	25	p-Phenylenediamine 对苯二胺
13	3,3'-dimethyl-4,4'-diaminodiphenylmethane 3,3'-二甲基-4,4'-二氨基二苯甲烷	26	Aniline 苯胺

\*\*\* End of Report \*\*\*

\*\*\* 报告结束 \*\*\*

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