

# REGULATION (EU) 2016 /425

## ANNEX III – TECHNICAL DOCUMENTATION FOR PPE

### SECTION 7 –USER INFORMATION AND PRODUCT MARKING

*(Include a copy of your user information and product marking/labels here. Ensure that you have fully addressed all requirements from the applicable harmonised standard or specification plus in addition to those of PPE Regulation (EU) 2016/425 Annex II Clause 1.4 – see section 6 of this file. Remember – always ensure that the instructions are clear and free from ambiguity).*

**Product:** Nitrile Metal Detectable Glove

**Product Name:** 5mil Double Tone Powder Free Nitrile Metal Detectable Gloves

**Specification:** Blue (outer) & Black (inner)

**Size:** 7.0 - Small (DTPFN MD002), 8.0- Medium (DTPFN MD003), 9.0- Large (DTPFN MD004), 10.0- Xtra Large (DTPFN MD005)

**Manufacturer:** GX Corporation Sdn Bhd (Specialty Plant)

**Address:** Plot 6497-A, Lorong Haji Abdul manan, 5 ¼ Milestone, Sementa, Jalan Kapar, 42100 Klang, Selangor Darul Ehsan

This product is classed as Personal Protective Equipment (PPE ) according to European PPE Regulation 2016/425 and has been shown to comply with this regulation through the Harmonised European Standards EN ISO 374-1:2016, EN ISO 388: 2016, EN ISO 374-5: 2016 (ISO 16604: 2004).

Notified Body responsible for the EU Type examination and ongoing conformity is SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, County Meath, D15 YN2P, Ireland.NB number 2777.

#### PERFORMANCE AND LIMITATION OF USE:

This product has been tested in accordance with EN 16523:2015, EN 374-4:2013, EN ISO 374-1:2016 and EN ISO 374-5:2016 (ISO 16604:2004), EN 388:2016 + A1:2018 (abrasion resistance) and achieved the following performance levels:

- 1) EN ISO 374-5:2016 - Protection against bacteria and fungi –Pass  
Protection against viruses – Pass  
\*The glove had been testing in accordance to ISO 16604: 2004- resistance to penetration by blood-borne pathogens to meet the requirements of EN ISO 374-5:2016.
- 2) Gloves does not meet the requirements as per EN 388:2016 + A1:2018 (abrasion resistance) with level of performance 1 due to estimated uncertainty of measurement applied at the point of test. This glove meets water leak test requirements for all sizes as per EN 374-2:2014. But this glove not suitable for air leak procedure.
- 3) EN 374-4:2013 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical. Testing results are from palm area of the glove.  
The penetration resistance has been assessed under laboratory conditions and relates only to tested specimen.
- 4) EN 16523-1: 2015 – Chemical permeation testing achieved as per below:

Requirement:

Performance level	1	2	3	4	5	6
Minimum breakthrough times (mins)	> 10	> 30	> 60	> 120	> 240	> 480

Remarks : “0” indicate that the gloves fall below the minimum performance level for the given individual hazard.

- Results for 9” (5mil) Double Tone Blue and Black Powder Free Metal Detectable Nitrile Finger Textured Gloves:

Chemicals	Code Letter	EN ISO 374-1:2016 Level Performance	EN 374-4:2013 Mean Degradation/ %	Permeation Breakthrough Time (min)
40% Sodium Hydroxide	K	6	-8.1	> 480
30% Hydrogen Peroxide	P	2	5.2	Between 31 and 45
37% Formaldehyde	T	4	0.4	Between 121 and 240

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**CAUTION:** Gloved used for protection against chemical must be selected especially for the type of chemicals used. Review level performance chemical for the chemical being used, to determine an adequate level of protection for the intended used.

These gloves are for **single use** only. Do not reuse. Do not use if contaminated. Properly dispose of all used nitrile glove. Follow your institution's policies for use and disposal of these gloves.

**FITTING AND SIZING** – Choose the appropriate glove size to avoid hand fatigue, see the hand guide on the wrapper, turn the cuff down to avoid drainage of chemicals onto the arm.

**STORAGE** – Keep ideally at 10C to 30C and 40% to 65% relative humidity. The durability of the product is 5 years from the date manufacturer. Once it opened, it is recommended to use the glove within 12 months.

**ALLERGY** - Components used in making this glove may cause allergic reactions in some people. Do not expose this glove to any person known or suspected to be sensitive to Nitrile or components used. If allergic reaction occurs discontinue use immediately and consult with a physician. Follow your institution's policies for use.

**HANDLING** – check before use, if you have chosen the glove that is suitable for the planned activity. Inspect the protective gloves for damage before use. Do not use damaged protective glove.

### **WARNING-**

#### **User instructions of chemical warnings for EN ISO 374-1:2016**

This information does not reflect the actual duration in the workplace and the differentiation between mixtures and pure chemicals.

The chemical resistance has been assessed under laboratory conditions from sample taken from the palm only (except in cases where the glove is equal to or over 400 mm, where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture.

It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on the temperature, abrasion and degradation.

When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movement, snagging rubbing, degradation caused by the chemical contact etc may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of the chemical resistant gloves.

Before usage, inspect the gloves for any defect or imperfections.

#### **User instructions of chemical warnings for EN ISO 374-5:2016**

The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

EN 374-4:2013, the degradation results indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

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## ANNEX III – TECHNICAL DOCUMENTATION FOR PPE

### ARTWORK MARKING:

- 5mil Double Tone Powder Free Nitrile Metal Detectable Glove
- Size: XS, S, M, L, XL
- Classification: Cat III
- Manufacturer: GX Corporation Sdn Bhd (Specialty Plant)  
Address: Plot 6497-A, Lorong Haji Abdul manan, 5 ¼ Milestone, Sementa, Jalan Kapar, 42100 Klang, Selangor Darul Ehsan
- Pictogram :

EN ISO 374-1:2016/Type B



KPT

ISO 374-5:2016



VIRUS

Marking of gloves protecting against virus,  
bacteria and fungi

CE 2777

SINGLE USE ONLY

Remarks: The user information/Instruction for used will be provided to end user as hard copy with the product.  
Also can be request at [info@smartglove.com.my](mailto:info@smartglove.com.my) or find at [www.smartglove.com.my](http://www.smartglove.com.my)