PRODUCT DATA SHEET

Product Code: 02-8-S

Sterile Nitrile Gloves - Chemotherapy

- Latex-Free
- High Chemotherapy Drug Resistance. Tested to ASTM D6978-05
- High Chemical Resistance
- High Puncture Resistance - Certified to ASTM F1342
- Suitable for Laboratory and PPE Use
- Lightweight Construction for High Sensitivity
- Gamma Sterilized
- Suitable for ISO 4-9 Cleanrooms

Nitrile gloves suitable for use in chemotherapy and cytotoxic applications, with a combination of chemical resistance and high material purity. Free from latex, sulphur and accelerators, they are a solution that guards the user against the main causes of contact dermatitis and natural rubber latex allergies.

It should be noted that drugs (and other chemicals) can permeate (go right through) an otherwise waterproof glove. This can lull clinicians into a false sense of security. In particular, most medical gloves have a very low resistance to the accidental spillage of cytotoxic chemotherapy drugs. This could pose a significant risk to clinical staff. This nitrile glove is different; its accelerator free formulation gives it remarkable resistance to the most aggressive chemotherapy drugs. The gloves are proven to resist permeation by chemotherapy drugs under ASTM D6978-05, having been tested against a wide range of chemotherapy drugs. See page 3 of this document for a complete list of tested drugs.

These gloves have tear and chemical resistance in compliance with to EN ISO 374, as well as complying with EN 455 sections 1 to 4 for single use medical gloves. This glove is also Gamma Sterilized, making it suitable for cleanrooms up to ISO class 4 (FED STD 209E Class 10).

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Technical Data

Colour:	White	**Thickness:**	Palm = 0.14mm
Material:	Nitrile		Cuff = 0.09mm
Sizes:	Medium (8)		Fingertips = 0.16mm
	Large (9)	**Packaging:**	1 pair/PE bag
	XL (10)		20 PE Bags/polybag
Glove Length:	33cm (approx.)		10 x polybags/carton

Certifications

CE CAT III

PPE Category III - includes risks that may lead to serious consequences such as death or irreversible damage to health, in accordance with PPE Regulation (EU) 2016/425 .

EN ISO 420:2003

EN 420:2003+A1:2009 - Protective gloves - General requirements and test methods.

EN ISO 374-1:2016 Type C

EN 374-1:2016 - Protective gloves against dangerous chemicals and micro-organisms (Part 1: Terminology and performance requirements for chemical risks). Type C indicates a breakthrough time of 10 minutes against minimum 1 test chemical.

EN ISO 374-5:2016

EN 374-5:2016 - Protective gloves against dangerous chemicals and micro-organisms (Part 5: Terminology and performance requirements for micro-organisms risks).

AQL 0.65

EN 455-1:2000 - Medical Gloves for single use (Part 1: Requirements and testing for freedom from holes)

ASTM D6978-05

ASTM D6978-05 - Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

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Test Results

Physical Properties

	Before Ageing		After Ageing	
Standard	**Tensile Strength**	**Elongation**	**Tensile Strength**	**Elongation**
ASTM D3577	> 17 MPa	> 650%	> 12 MPa	> 490%
EN 455-2	Force at Break: min. 9 Newtons		Force at Break: min. 6 Newtons	

Resistance to Penetration (EN 374-2:2014)

Performance Level	Acceptable Quality Limit (AQL)	Inspection Level	02-8-N Result
3	< 0.65	G1	AQL = 0.65
2	< 1.50	G1	
1	< 4.00	S4	

Performance Results for Micro-Organism Risk (EN ISO 374-5:2016)

Size	Medium	Large	XL
Total Length (±10mm)	330mm	330mm	330mm
Palm Width (±3mm)	91mm	106mm	118mm
Weight Per Piece (±0.5g)	8.6g	9.8g	11.0g

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Resistance to Permeation by Chemicals (EN 371-1) and Resistance to Degradation by Chemicals (EN 374-4)

Breakthrough Time (mins)	Performance Level for Permeation
> 10	1
> 30	2
> 60	3
> 120	4
> 240	5
> 480	6

Protective gloves against chemicals are classified in three types, based on their permeation performance against the test chemicals listed in the table below:

- Type A: Must satisfy at least Level 2 for a minimum of 6 test chemicals
- Type B: Must satisfy at least Level 2 for a minimum of 3 test chemicals
- Type C: Must satisfy at least Level 1 for a minimum of 1 test chemical

Chemical	Performance Level*	Breakthrough Time (mins)	Mean Degradation/%**
Isopropanol 70%	3	64 mins	57.2
Ethanol 70%	1	22 mins	-44.5
Sodium hydroxide 50%	6	> 480 mins	12.9
Hydrochloric Acid 37%	4	202 mins	46.6
Sulphuric Acid 50%	6	> 480 mins	34.4
Hydrogen Peroxide 30%	5	361 - 480 mins	-36.5

*Performance levels are based on the lowest individual result achieved per chemical.

**Where the test specimens gave an increased puncture force after chemical exposure, the test result is reported as a negative degradation.

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Permeation Tests with Cytostatic Drugs According to ASTM D6978-5

Test Chemotherapy Drug	Average Breakthrough Time (mins)
Carboplatin	> 240
Carmustine	60
Cisplatin	> 240
Cyclophosphamide (Cytoxan)	> 240
Dacarbazine (DTIC)	> 240
Daxorubicin Hydrochloride	> 240
Etoposide (Toposar)	> 240
5-Fluorouracil	> 240
Ifosfamide	> 240
Methotrexate	> 240
Mitomycin	> 240
Mitoxantrone	> 240
Paclitaxel (Taxol)	> 240
ThioTEPA	160

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