

Toruńskie Zakłady Materiałów Opatrunkowych SA	
Toruńskie Zakłady Materiałów Opatrunkowych S.A. ul. Żółkiewskiego 20/26 87-500 Toruń Tel. 056 612 39 00, fax 056 612 33 96 NIP 879-016-67-90	TECHNICAL DATA SHEET
	GLOVES
	DIAGNOSTIC/EXAMINATION GLOVES non sterile
TDS – GLOVE – 02	

1. Product description

Diagnostic/examination gloves have a universal shape and a rolled cuff.

2. Application

Diagnostic/examination gloves are intended for performing medical examinations, diagnostic or therapeutic procedures and handling contaminated or soiled material.

3. Technical parameters

REQUIREMENTS		CHARACTERISTICS					
		Ambulex	Ambulex P	Ambulex Nitryl			
				Blue	White	Black	Violet
Compliance with EN 455		YES	YES	YES	YES	YES	YES
Compliance with EN 420		YES	YES	YES	YES	YES	YES
Compliance with EN ISO 374-1 (including -2 and -4) and 374-5		YES	YES	YES	YES	YES	NO
Compliance with EN ISO 10993-5		YES	YES	YES	YES	YES	NO
Compliance with EN ISO 10993-10		YES	YES	YES	YES	YES	NO
Compliance with ISO 11193-1		YES	YES	YES	YES	YES	NO
Compliance with ASTM F1671		YES	YES	YES	YES	YES	NO
Compliance with ASTM D3578		YES	YES	NO	NO	NO	NO
Compliance with ASTM D5712		YES	YES	NO	NO	NO	NO
Compliance with ASTM D5151		YES	YES	YES	YES	YES	NO
Compliance with ASTM D6124		YES	YES	YES	YES	YES	NO
Compliance with ASTM D6319		DOES NOT CONCERN	DOES NOT CONCERN	YES	YES	YES	YES
Compliance with ASTM D7160		YES	YES	YES	YES	YES	NO
Compliance with ASTM D7161		YES	YES	YES	YES	YES	NO
Admission to food contact*		YES	YES	YES	YES	YES	YES
No content of thiurams		YES	YES	YES	YES	YES	YES
Production conditions compliant with	GMP	YES	YES	YES	YES	YES	NO
	ISO 14001						
	OHSAS 18001						
	BSCI						

* Confirmed with the certificate of an independent unit

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Ambulex, Ambulex P, Ambulex Nitrile (Blue, White, Black) gloves were tested in accordance with EN 16523-1. Detailed information on the resistance of gloves to chemicals is available at your medical representative.

Ambulex Nitril gloves (Blue) meet the requirements of ASTM D6978. Detailed information on the resistance of gloves to cytotoxic drugs is available at your medical representative.

REQUIREMENTS	CHARACTERISTICS	
	Ambulex VINYL	
	powder-free	powdered
Compliance with EN 455	YES	YES
Compliance with EN 420	YES	YES
Compliance with EN ISO 10993-5	YES	YES
Compliance with EN ISO 10993-10	YES	YES
Admission to food contact	YES	YES
No content of dioctyl phthalate (DOP, DEHP)	YES	YES

3.1. Glove sizes


PARAMETRE			VALUE					TEST METHOD
			XS	S	M	L	XL	
Length [mm]		Latex, Vinyl, Nitrile (blue, black, purple)	≥ 240					EN 455-2
Length [mm]		Nitrile white	≥ 265					
Width [mm]			≤ 80	80 ± 10	95 ± 10	110 ± 10	≥ 110	
Latex	Thickness* [mm]	Fingers	powder-free			powdered		-
			≥ 0.24			≥ 0.20		
		Palm	≥ 0.20			≥ 0.16		
			Cuff	≥ 0.14			≥ 0.12	
Nitrile	Thickness* [mm]		Blue	White	Black	Violet		-
		Fingers	≥ 0.14	≥ 0.16	≥ 0.20	≥ 0.10		
		Palm	≥ 0.12	≥ 0.12	≥ 0.14	≥ 0.10		

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		Cuff	≥ 0.10	≥ 0.10	≥ 0.10	≥ 0.08	
Vinyl	Thickness* [mm]	Fingers	≥ 0.12				-
		Palm	≥ 0.10				
		Cuff	≥ 0.10				

3.2. Types of gloves

PARAMETRE	CHARACTERISTICS		TEST METHOD
	Ambulex	Ambulex P	
	Powdered	Powder-free	
Colour	Creamy	Creamy	-
Type	latex	latex	-
Raw material	natural rubber latex	natural rubber latex	-
Coating	internally coated with natural corn starch	internally polymer-coating	-
Protein level	≤ 85 µg/g	≤ 30 µg/g	EN 455-3
Powder level	≤ 10 mg/dm ²	≤ 2 mg/glove	EN 455-3
Surface	smooth, rough fingers	rough	-
Elongation [%]	700 ÷ 760	720 ÷ 780	-
Tensile strength before aging [N]	6.3 ÷ 8.0		EN 455-4
Tensile strength after aging [N]	6.3 ÷ 7.1		EN 455-4
Required level of the absence of holes [AQL]	1.5		ISO 2859-1
Level of gripping capacity	5		EN 420+A1


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PARAMETRE	CHARACTERISTICS						TEST METHOD
	Ambulex NITRYL				Ambulex VINYL		
	Powder-free				Powdered	Powder-free	
Colour	Blue	White	Black	Violet	No colour	No colour	-
Type	nitrile				vinyl		-
Raw material	acrylonitrile-butadiene rubber				polyvinylchloride		-
	Blue	White	Black	Violet			
Coating	internally chlorinated				internally powdered with natural corn starch	internally polymer-coating	-
Level of proteins	-				-	-	EN 455-3
Level of powder	≤ 2 mg/glove				≤ 10 mg/glove	≤ 2 mg/glove	EN 455-3
Surface	smooth, rough fingers				smooth		-
Elongation [%]	400 ÷ 500			350 ÷ 450	175 ÷ 230	185 ÷ 240	-
Tensile strength before aging [N]	7.0 ÷ 7.5	7.0 ÷ 7.5	8.0 ÷ 9.0	6.0 ÷ 7.0	3.6 ÷ 3.9		EN 455-4
Tensile strength after aging [N]	7.0 ÷ 7.5	7.0 ÷ 7.5	8.0 ÷ 9.0	6.0 ÷ 7.0	3.6 ÷ 3.7		EN 455-4
Required level of the absence of holes [AQL]	1.5						ISO 2859-1
Level of gripping capacity	5						EN 420+A1

4. Validity period

Product shelf life – 5 years from the production date.

5. Storage, transportation

Storage and transportation conditions are as set out in appendix **Storage and transportation conditions for TZMO products.**

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6. Standards

The products are compliant with the following standards:

- EN 455-1 Medical gloves for single use – Part 1: Requirements and testing for freedom from holes
- EN 455-2 Medical gloves for single use – Part 2: Requirements and testing for physical properties
- EN 455-3 Medical gloves for single use – Part 3: Requirements and testing for biological evaluation
- EN 455-4 Medical gloves for single use – Part 4: Requirements and testing for shelf life determination
- EN 420 Protective gloves – general requirements and test methods
- EN ISO 374-1 Protective gloves against dangerous chemicals and micro-organisms -- Part 1: Terminology and performance requirements for chemical risks
- EN 374-2 Protective gloves against dangerous chemicals and micro-organisms — Part 2: Determination of resistance to penetration
- EN 16523-1 Determination of material resistance to permeation by chemicals – Part 1: Permeation by liquid chemical under conditions of continuous contact
- EN 374-4 Protective gloves against chemicals and micro-organisms -- Part 4: Determination of resistance to degradation by chemicals
- EN ISO 374-5 Protective gloves against dangerous chemicals and micro-organisms -- Part 5: Terminology and performance requirements for micro-organisms risks
- EN ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitisation
- ISO 11193-1 Single-use medical examination gloves
- ISO 2859-1 Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

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- ASTM F1671 Standard test method for resistance of material used in protective clothing to penetration by blood-borne pathogens using Phi-X174 bacteriophage penetration as a test system
- ASTM D3578 Standard specification for rubber examination gloves
- ASTM D5712 Standard test method for analysis of aqueous extractable protein in latex, natural rubber, and elastomeric products using the modified Lowry method
- ASTM D5151 Standard test method for detection of holes in medical gloves
- ASTM D6124 Standard test method for residual powder on medical gloves
- ASTM D6319 Standard specification for nitrile examination gloves for medical application
- ASTM D6978 Standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs
- ASTM D7160 Standard practice for determination of expiration dating for medical gloves
- ASTM D7161 Standard practice for determination of real time expiration dating of mature medical gloves stored under typical warehouse conditions
- GMP Good manufacturing practices
- ISO 14001 Environmental management systems -- Requirements with guidance for use
- OHSAS 18001 Occupational health and safety management systems – Specification
- BSCI Business Social Compliance Initiative


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