

# TECHNICAL DATA SHEET

## TDS-GLOVE-02



### GLOVES

EXAMINATION AND DISPOSABLE PROTECTIVE GLOVES, non sterile

#### I. PRODUCT DESCRIPTION

Diagnostic, Personal Protective Equipment (PPE), universal shape and a rolled cuff.

#### II. APPLICATION

They are intended for performing medical examinations, diagnostic or therapeutic procedures and handling contaminated or soiled material.

#### III. CHARACTERISTIC

##### COMPLIANCE WITH STANDARDS

REQUIREMENTS	CHARACTERISTICS					
	Ambulex -004	Ambulex P -006	Ambulex NITRYL -017 (black)	Ambulex NITRYL -018 (white)	Ambulex NITRYL -020 (white long)	Ambule x NITRYL -021 (violet)
Compliance with EN 455	YES	YES	YES	YES	YES	YES
Compliance with EN 420 (new edition EN ISO 21420)	YES	YES	YES	YES	YES	YES
Compliance with EN ISO 374-1, -2, -4 and -5	YES	YES	YES	YES	YES	YES
Compliance with EN 16523-1*	YES	YES	YES	YES	YES	YES

<b>Compliance with EN ISO 10993-5</b>	YES	YES	YES	YES	YES	YES
<b>Compliance with EN ISO 10993-10</b>	YES	YES	YES	YES	YES	YES
<b>Compliance with ISO 11193-1</b>	YES	YES	YES	YES	YES	YES
<b>Compliance with ASTM F1671</b>	YES	YES	YES	YES	YES	YES
<b>Compliance with ASTM D3578</b>	YES	YES	DOES NOT CONCERN	DOES NOT CONCERN	DOES NOT CONCERN	DOES NOT CONCERN
<b>Compliance with ASTM D5712</b>	YES	YES	DOES NOT CONCERN	DOES NOT CONCERN	DOES NOT CONCERN	DOES NOT CONCERN
<b>Compliance with ASTM D5151</b>	YES	YES	YES	YES	YES	YES
<b>Compliance with ASTM D6124</b>	YES	YES	YES	YES	YES	YES
<b>Compliance with ASTM D6319</b>	DOES NOT CONCERN	DOES NOT CONCERN	YES	YES	YES	YES
<b>Compliance with ASTM D7160</b>	YES	YES	YES	YES	YES	YES
<b>Compliance with ASTM D7161</b>	YES	YES	YES	YES	YES	YES
<b>Admission to food contact**</b>	YES	YES	YES	YES	YES	YES
<b>No content of thiurams</b>	YES	YES	YES	YES	YES	YES
<b>Production conditions compliant with: GMP, ISO 14001, ISO 45001, BSCI</b>	YES	YES	YES	YES	YES	YES

\*Detailed information on the resistance of gloves to chemical substances can be found in the appendices: TDS-APP-019 and TDS-APP-021.

\*\*Confirmed with the certificate of an independent unit.

Ambulex NITRYL -017, -018, -020, -021 conform to the requirements of ASTM D6978. Detailed information on the resistance of gloves to cytostatic drugs can be found in the appendix: TDS-APP-020.

## TECHNICAL PARAMETERS

### Types of latex gloves:

PARAMETER	CHARACTERISTICS		TEST METHOD
	Ambulex -004	Ambulex P -006	
	powdered	powder-free	
Colour	creamy		-
Type	latex		-
Raw material	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 <sup>2</sup>	≤ 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

**Types of nitrile gloves:**

PARAMETER	CHARACTERISTICS				TEST METHOD
	Ambulex NITRYL -017 (black)	Ambulex NITRYL -018 (white)	Ambulex NITRYL -020 (white long)	Ambulex NITRYL -021 (violet)	
	powder-free				
Type	nitrile				-
Raw material	acrylonitrile-butadiene rubber				-
Coating	internally chlorinated				-
Protein level	-				EN 455-3
Powder level	≤ 2 mg/glove				EN 455-3
Surface	smooth, rough fingers				-
Elongation [%]	400 - 500				-
Tensile strength before aging [N]	8.0 - 9.0	7.0 - 7.5		6.0 - 7.0	EN 455-4
Tensile strength after aging [N]	8.0 - 9.0	7.0 - 7.5		6.0 - 7.0	EN 455-4
Required level of the absence of holes [AQL]	≤ 1.5				ISO 2859-1
Level of gripping capacity	5				EN 420+A1

## PHYSICAL PARAMETERS

PARAMETER		Ambulex -004	Ambulex P -006	Ambulex NITRYL -017 (black)	Ambulex NITRYL -018 (white)	Ambulex NITRYL -020 (white long)	Ambulex NITRYL -021 (violet)	TEST METHOD
Thickness* [mm]	Fingers	≥ 0.10	≥ 0.12	≥ 0.09	≥ 0.07	≥ 0.07	≥ 0.05	-
	Palm	≥ 0.08	≥ 0.10	≥ 0.06	≥ 0.06	≥ 0.06	≥ 0.05	
	Cuff	≥ 0.06	≥ 0.07	≥ 0.05	≥ 0.05	≥ 0.05	≥ 0.04	
Length [mm]	XS	≥ 240				≥ 265	≥ 240	EN 455-2
	S							
	M							
	L							
	XL							
Width [mm]	XS	≤ 80						EN 455-2
	S	80 ± 10						
	M	95 ± 10						
	L	110 ± 10						
	XL	≥ 110						

\*Thickness of single layer

**The products are compliant with the following standards (for gloves as in the table "Compliance with 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 method
- EN ISO 374-1 Protective gloves against dangerous chemicals and micro-organism - Part 1: Terminology and performance requirements for chemical risk
- EN ISO 374-2 Protective gloves against dangerous chemicals and micro-organism - 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 ISO 374-4 Protective gloves against dangerous chemicals and micro-organism - Part 4: Determination of resistance to degradation by chemicals
- EN ISO 374-5 Protective gloves against dangerous chemicals and micro-organism - Part 5: Terminology and performance requirements for micro-organism risks
- EN ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitisation
- EN ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- 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
- 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 Glove
- 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
- ISO 45001 Occupational health and safety management systems - requirements with guidance for use
- BSCI Business Social Compliance Initiative

## I. SHELF LIFE

---

The expiry date is 5 years from the production date for Ambulex, Ambulex P, Ambulex NITRYL -018, Ambulex NITRYL -020, Ambulex NITRYL -017 and 4 years for Ambulex NITRYL -021.

---

## II. STERILISATION

---

The product is supplied non-sterile.

---

## III. STORAGE, TRANSPORTATION

---

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

---

### Created by:

Medical Device Safety Vigilance Specialist  
Magdalena Jaćkowska-Terzyk

### Approved by:

TZMO SA Chief Technologist  
Jan Rosiński

---

Date of creation / update: according to the signature card

---

## poświadczenie złożenia podpisów i pieczęci elektronicznych

Certyfikat dla dokumentu o Autenti ID: 602eb60c-2ff0-4bfd-8d33-328f06485518  
utworzonego: 2021-09-24 09:01 (GMT+02:00)