



DECLARATION OF CONFORMITY

Product: **NITRILE GLOVES
LATEX GLOVES**

We declare that the above mentioned product satisfies the requirements laid down in MDD 93/42/EEC, as amended by the Council directive 2007/47/EC.

We, moreover, declare and guarantee that

- the above mentioned product satisfies all necessary requirements as recommended in Annex VII of Medical Device Directive 93/42/EEC, as amended by the Council directive 2007/47/EC.
- the above mentioned product belongs to Class I
- the above mentioned product satisfies the European Standards EN 455 part 1, 2 & 3 – Part 4 in Process
- the above mentioned product is sold in non-sterile packaging

Akzenta International SA

Chiasso, 01.01.2019



STYLE NITRILE GLOVES

SINGLE USE DISPOSABLE NITRILE EXAMINATION GLOVES

CONFIGURATION OVERVIEW

Features:

- Cuff strengthened by a rolled cuff
- Easy donning and removal
- Excellent tactile sensibility (Micro textured fingertips)

Shape:

- Ambidextrous

Material:

- Nitrile

Type:







- Non-Sterile
- Powder-free
- Latex-free

QUALITY ASSURANCE

Quality certification:

- ISO 9001 :2008, ISO 13485:2003, ISO14001:2004, OHSAS 18001:2007
- Class I Medical Device as per MDD 93/42/EEC
- (Conform to EN part 1, 2, 3 & 4 and ISO 10993 Biological Evaluation)
- PPE Directive 89/686/EEC – CAT III
- (Conform to EN 374, EN388 & EN420)
- Product compliance with Regulation (EC) no 1935/2004 & meeting demand of Commission Regulation (EU) no 10/2011

PRODUCT VARIATIONS

Art-No.	STYLE1-AZ-MB-	STYLE1-AZ-P-	STYLE1-AZ-L-	STYLE1-AZ-FG-	STYLE1-AZ-O-	STYLE1-AZ-F-	STYLE1-AZ-WR-
Color	Med Blue	Pink	Lilac	Fresh Green	Orange	Fuchsia	Burgundy
							

Available Size: XS S M L

TECHNICAL SPECIFICATIONS

Physical Properties:

Elongation at Break (%)	≥500%
Force Break (N)	≥6N

Location of Thickness Measurement	Finger Tip	Palm	Cuff
Single Wall (mm)	≥ 0.08	≥ 0.05	≥ 0.04

Available Length:

- ≥ 240 mm / 270 mm

Weight M size:

- 3.2 g ± 0.2 g

Shelf life:

- 3 years

PACKAGING

Pcs/dispenser	100	Dispenser/carton	10
Carton size	26x25,2x25,2 cm	Carton weight	3.5 kg (XS), 3.8 kg (S), 4.0 kg (M), 4.5 KG (L)
Carton/layer	12	Layers/pallet	7
Carton/pallet	84	Pallet weight	314 kg (XS), 339.2 kg (S), 356 kg (M), 398 kg (L)
Pallet size	80x120x191,4 cm		



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CONFIGURATION OVERVIEW

Features	Cuff strengthened by a rolled cuff Easy donning and removal Excellent tactile sensibility (Micro textured fingertips)
Shape:	Ambidextrous
Material:	Nitrile
Type:	Non-Sterile Powder-free Latex-free

TECHNICAL SPECIFICATIONS

Physical Properties:

Elongation at Break (%)	≥500%
Force Break (N)	≥6N
Location of Thickness Measurement	Single Wall (mm)
Finger Tip	≥ 0.08
Palm	≥ 0.05
Cuff	≥ 0.04

Available Length:	≥ 240 mm /270 mm
Weight M size:	3.2 g ± 0.2 g
Shelf life:	5 years

QUALITY ASSURANCE

Quality certification:

Class I Medical Device as per MDD 93/42/EEC
(Conform to EN part 1, 2, 3 & 4 and ISO 10993 Biological Evaluation)
PPE Directive 89/686/EEC – CAT III
(Conform to EN 374, EN388 & EN420)
Product compliance with Regulation (EC) no 1935/2004 & meeting demand of Commission Regulation (EU) no 10/2011
Produced under ISO 13485:2003 and ISO 13485:2008 Quality Management
Produced under ISO 14001:2004 Environmental Management
Produced under OHSAS 18001:2007 Safety & Health Management

PRODUCT VARIATIONS

Art-No.	STYLE1-AZ-MB-	STYLE1-AZ-P-	STYLE1-AZ-L-	STYLE1-AZ-FG-	STYLE1-AZ-O-	STYLE1-AZ-F-	STYLE1-AZ-LB-
Color	Med Blue	Pink	Lilac	Fresh Green	Orange	Fuchsia	Laguna Blue

Available Size: XS S M L

