

Specification Sheet - Medguard Elite Nitrile Powder Free Examination Gloves

Material	Synthetic Rubber Nitrile
Colour	Blue
Design & Feature	Ambidextrous, full textured, beaded cuff
Powdered	No
Sterile	No
Type	Single chlorination
Latex Free	Yes



Glove Specifications:

Size	Palm Width (mm)	Force @ Break (newton)	
		Unaged	Aged
Extra Small	75 ± 5	≥6N	≥6N
Small	85 ± 5		
Medium	95 ± 5		
Large	106 ± 5		
Extra Large	116 ± 5		
Cuff Thickness	≥0.08	Available Length	≥240mm
Palm Thickness	≥0.10	Shelf Life	3 Years
Finger Thickness	≥0.12	Weight M Size	5.4 ± 0.2g

Conformity Standards:

Class I Medical Device as per Medical Device Regulation (EU) 2017/745 (Conform to EN 455 part 1, 2, 3 and 4 and ISO 10993 Biological Evaluation)	CE
PPE Regulation (EU) 2016/425 – CAT I, (Conform to EN ISO 374)	CE
Produced under ISO 13485:2016 & EN ISO 13485:2016 Quality Management	BSI UKAS Quality Management
Produced under ISO 9001:2015 Quality Management	BSI, IAF, ANAB

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Assessments: Batch test certificate for each order

Defects	Inspection Level	AQL
Pinholes	G-I	1.5
Visual Defects (Major)	G-I	2.5
Visual Defects (Minor)	G-I	4.0
Physical Dimensions	N=13	Median value must comply
Physical Properties	N=13	Median value must comply

External Quality Assessment and Risk Assessment

Testing	Standard Reference	Max Acceptable Level	Remarks
Allergy Skin Irritation Test	ISO 10993-10:2010	PII (Primary Irritation Index) <0.4	No allergy (Oedema: 0/3, Erythema: 0/3), PII=0 (Pass)
Allergy Skin Sensitisation Test	ISO 10993-10:2010	Oedema: <1, Erythema <1	No allergy (Oedema: 0/10, Erythema: 0/10) (Pass)
Cytotoxicity	ISO 10993-5:2009	"Not Applicable"	Grade 4 at 100% of extract

In Compliance With:

- CODE OF CONDUCT – For Industrial Harmony and CSR
- REACH – Authorisation and Restriction of Chemicals

Key Benefits:

- BEST SELLER, premium quality blue nitrile glove, which offer superior puncture protection
- Excellent for high-risk situations involving infectious material
- Powder free which reduces potential dust contamination & minimises the drying effects of powder on skin
- Beaded cuff with exceptional tensile strength to prevent roll down issue
- Provides outstanding comfort and ease of movement
- Latex free which reduces the risk of allergic reactions and hypersensitivity
- Free of protein, thiuram pesticides, plasticizer, animal tissue and other biological substances
- Blue colour makes them easily identifiable in comparison to latex
- Textured fingertips for superior control and tactile sensitivity
- Suitable for use in all medical and catering environments

Ordering Information

CS-7001	Extra Small (100 x 10)
CS-7002	Small (100 x 10)
CS-7003	Medium (100 x 10)
CS-7004	Large (100 x 10)
CS-7005	Extra Large (90 x 10)