



TECHNICAL CHARACTERISTICS

Material: Nitrile
Color: Blue
AQL: 1.0
Sterility: Non sterile

High comfort, dexterity and resistance to perforation and puncture; High elasticity which confers high adaptability. Anatomically adjustable beaded cuff. Micro-textured thimbles ends for an adequate sensibility. Ambidextrous. Single use. Latex free, with a low risk to allergies.

INTENDED PURPOSE OF THE PRODUCT

For use by health professionals in hospital environment, with the purpose to cover their hands and ensure the patient adequate protection against possible contamination.

CLASSIFICATION

Medical Device of Class I, non-sterile, in compliance with Regulation (EU) 2017/745.
Personal Protective Equipment of Category III, in compliance with Regulation (EU) 2016/425.
Notified Body 2797 (BSI Group the Netherlands B.V.), in the PPE Certification, as Category III.

STANDARDS AND DIRECTIVES APPLIED

Medical Device of Class I, non-sterile, in compliance with Regulation (EU) 2017/745.
Tested under the Standards: EN 455-1:2000; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009.
Personal Protective Equipment of Category III, in compliance with Regulation (EU) 2016/425. Tested under the Standards: EN 420:2003+A1:2009; EN ISO 374-1:2016+A1:2018; EN ISO 374-2:2019; EN ISO 374-4:2019; EN ISO 374-5:2016; EN 16523-1:2015+A1:2018; ISO 16604:2004.

STORAGE AND TRANSPORT RECOMMENDATIONS

Keep in a dry place and protect from the humidity, direct sunlight, fluorescent light, ozone, X-rays and freezing and excessive heat. Dispose of in accordance with local regulations.

VALIDITY

3 Years, after manufacture's date.

LOGISTIC

Carton with 1000 units.

SYMBOLOLOGY APPLIED



MANUFACTURER

Raclac, S.A.

Blue Nitrile Examination Gloves, powder-free

References: FP.RE1301.S | FP.RE1301.M | FP.RE1301.L



PHYSICAL CHARACTERISTICS

		Specifications	Inspection level AQL
Width (mm)	S	80 ± 10	S2/AQL 4.0
	M	95 ± 10	
	L	110 ± 10	
Length (mm)	All sizes	≥240	S2/AQL 4.0
Thickness (mm)	Cuff	0.05 ± 0.01	S2/AQL 4.0
	Palm	0.06 ± 0.01	
	Finger	0.09 ± 0.01	
Weight (gr/glove)	S	2.8 ± 0.2	S2/AQL 4.0
	M	3.0 ± 0.2	
	L	3.2 ± 0.2	

CHEMICAL PROTECTION

Chemical code letter	Chemical Name	Permeation Level of protection	Degradation (%)
K	40% Sodium Hydroxide	6	-64.8%

MECHANICAL CHARACTERISTICS

		Specifications	AQL inspection level
Before aging	Tensile Strength	14 Mpa (min)	S2/AQL 4.0
	Ultimate elongation	500% (min)	
After aging	Tensile Strength	14 Mpa (min)	
	Ultimate elongation	500% (min)	
EN 455-2		≥ 6 N	

REQUIREMENTS AQL

Type	Non Conformities	Inspection level	AQL
Water resistance	Holes, under EN 455-1	G1	1.0
Dimensions	Wight, Length, Thickness, under EN 455-2	S2	4.0
Visual	Discoloration, dirtiness, spots	S4	4.0