

# easyCARE nitrile black

## Nitrile examination gloves, powder-free

### TD-49

Attachment No. 3  
point 2 pp. 2.3

Revision V  
2020.04.01

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#### PRODUCT CHARACTERISTICS:

- made of synthetic rubber, free of latex proteins, which has a positive effect on the comfort of people sensitive to latex proteins
- characterized by good resistance to oils, greases and many toxic chemicals and solvents. Nitrile gloves have high resistance to abrasion and puncture

#### FEATURES:

- Raw material:** 100% nitrile (acrylonitrile butadiene)
- Colour:** black
- Cuff:** beaded
- Powder:** powder free; the content of powder residue below 2 mg per glove
- Latex protein level:** 0
- AQL:** 1.0
- Internal surface:** chlorinated
- Perfect grip both in dry and wet conditions** secure grip thanks to the texture at the fingertips
- Classification:** class I Medical Device in accordance with MDR Regulation (EU) 2017/745. Personal Protective Equipment Category III according to PPE Regulation (EU) 2016/425
- Standards:** in accordance with the requirements of EN 455, EN 374-2,4; resistant to the penetration of viruses and microorganisms in accordance with EN ISO 374-5 and ASTM F1671, tested for the penetration of chemicals according to EN ISO 374-1 (type B) in accordance with EN 16523; comply with EN 420; approved for contact with food
- Quality Assurance System:** manufacturing process in accordance with EN ISO 9001 and EN ISO 13485
- Individual packaging:** 100 pcs in colour-coded boxes for size recognition
- Shelf life:** 5 years
- Sizes:** XS-XL



#### SIZE AND REFERENCE

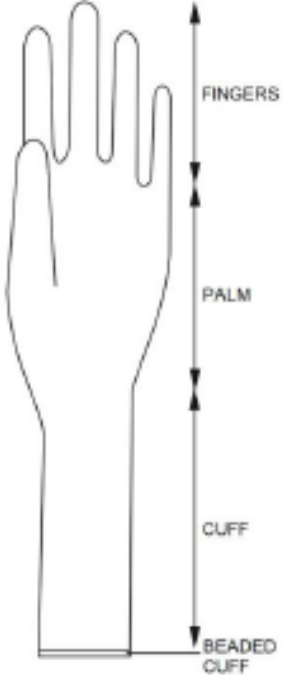
CATALOGUE NUMBER	SIZE	INTERMEDIATE PACKAGING	BULK PACKAGING
RNBC03XS	XS	100 pcs	10 x 100 pcs
RNBC03S	S	100 pcs	10 x 100 pcs
RNBC03M	M	100 pcs	10 x 100 pcs
RNBC03L	L	100 pcs	10 x 100 pcs
RNBC03XL	XL	100 pcs	10 x 100 pcs

	Technical data sheet	Attachment no. 6 pt. 1 subpt. 1.1
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<b>MEDICAL DEVICE / PERSONAL PROTECTIVE EQUIPMENT DATA:</b>		
<b>CATALOGUE NUMBER</b>	RNBC03XS, RNBC03S, RNBC03M, RNBC03L, RNBC03XL	
<b>MANUFACTURER</b>		
<b>CLASSIFICATION</b>	Class I Medical Device, rule 1 in accordance with MDR Regulation (EU) 2017/745 Personal Protective Equipment Category III according to PPE Regulation (EU) 2016/425	
<b>METHOD OF STERILIZATION</b>	N/A / non-sterile	<b>CODE OF GENERIC DEVICE GROUP ACCORDING TO UMDNS</b> 20932
<b>PERFORMANCE CHARACTERISTICS</b>	non-sterile, powder-free examination gloves for single use; made of synthetic rubber, they are an alternative solution for people with allergies to natural latex rubber provide a barrier against microorganisms to the user and the patient; allow the risk of infection to be minimized	
<b>CURRENT TECHNICAL STANDARDS ARE APPLICABLE TO THE DEVICE</b>	EN 455-1,2,3,4 - Medical gloves for single use EN ISO 374-1,5 - Protective gloves against dangerous chemicals and micro-organisms EN 374-2,4 - Protective gloves against dangerous chemicals and microorganisms EN 16523-1- Determination of material resistance to permeation by chemicals EN 420 - Protective gloves ASTM F1671 - Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X 174 Bacteriophage Penetration as a Test System	

<b>TECHNICAL DATA:</b>	
<b>RAW MATERIALS</b>	100% nitrile (acrylonitrile butadiene)
<b>WEIGHT</b>	4.0 ± 0.2g
<b>COLOUR</b>	black
<b>FEATURES</b>	<ul style="list-style-type: none"> <li>▪ cuff: beaded</li> <li>▪ powder free, the content of powder residue below 2 mg per glove</li> <li>▪ AQL: 1.0</li> <li>▪ texture at the fingertips</li> <li>▪ internal surface: chlorinated</li> <li>▪ shape: ambidextrous, fitting to the right and left hand</li> <li>▪ single-use</li> </ul>
<b>SIZES</b>	XS, S, M, L, XL
<b>SHELF LIFE</b>	5 years

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<b>TECHNICAL DRAWING</b>				
	<b>DETAILED DIMENSIONS / SPECIFICATION</b>	REF	SIZE	WIDTH OF PALM (mm)
	RNBC03XS	XS (5-6)	≤ 80	min. 240
	RNBC03S	S (6-7)	80±10	min. 240
	RNBC03M	M (7-8)	95±10	min. 240
	RNBC03L	L (8-9)	110±10	min. 240
	RNBC03XL	XL (9-10)	≥ 110	min. 240
<b>THICKNESS</b>	PART OF GLOVE		SINGLE WALL (mm)	
	finger ( 13mm from the tip )		0,11±0,02	
	palm ( in the middle part )		0,08±0,02	
	cuff		0,07±0,01	
<b>PHYSICAL PROPERTIES</b>	PARAMETER		BEFORE AGING	AFTER AGING
	tensile strength (MPa)		min. 14	min. 14
	elongation (%)		min. 500	min. 400
	force at break (N)		min. 6,0	min. 6,0
<b>PACKAGING</b>		<b>number of pieces</b>	<b>packaging material</b>	<b>packaging dimensions</b>
	<b>intermediate packaging</b>	100 pcs	flat cardboard - a cardboard box with a perforation to open, CMYK printing	20x11x6cm
	<b>bulk packaging</b>	10 x 100 pcs	carton - corrugated cardboard with printing	31,5x23x21cm
<b>STORAGE CONDITIONS</b>	<b>temperature:</b>	5°C - 35°C		
	Store in a cool, dry, well ventilated and clean location; Keep out of direct sunlight. Keep away from sources of ozone or ignition. Gloves should be kept in their original packaging.			