

easyCARE nitrile

Nitrile examination gloves, powder-free

TD-49

Attachment No. 3
point 2 pp. 2.3

Revision II
2020.04.01

Page 1/1

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:** blue
- Cuff:** beaded
- Powder:** powder free; the content of powder residue below 2 mg per glove
- 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 or 200 pcs in colour-coded boxes for size recognition
- Shelf life:** 3 years
- Size:** XS-XL



SIZE AND REFERENCE

CATALOGUE NUMBER	SIZE	INTERMEDIATE PACKAGING	BULK PACKAGING
RNB-XS-100	XS	100 pcs	10 x 100 pcs
RNB-S-100	S	100 pcs	10 x 100 pcs
RNB-M-100	M	100 pcs	10 x 100 pcs
RNB-L-100	L	100 pcs	10 x 100 pcs
RNB-XL-100	XL	100 pcs	10 x 100 pcs
RNB-XS-200	XS	200 pcs	10 x 200 pcs
RNB-S-200	S	200 pcs	10 x 200 pcs
RNB-M-200	M	200 pcs	10 x 200 pcs
RNB-L-200	L	200 pcs	10 x 200 pcs
RNB-XL-200	XL	200 pcs	10 x 200 pcs

Technical data sheet

Attachment no. 6
pt. 1 subpt. 1.1

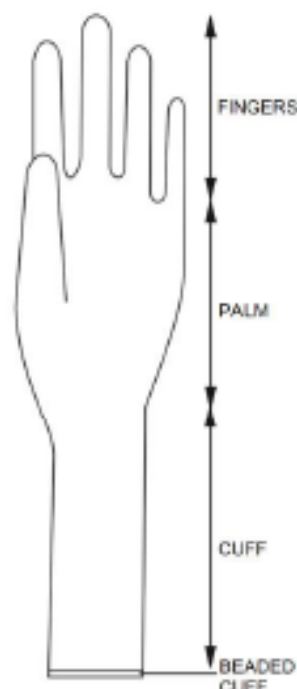
TD-49 easyCARE nitrile

Edition II
2020.04.01

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Page 2/2

TECHNICAL DRAWING



DETAILED DIMENSIONS / SPECIFICATION

REF	SIZE	WIDTH OF PALM (mm)	LENGTH OF A GLOVE (mm)
RNB-XS-100	XS (5-6)	≤ 80	min. 240
RNB-S-100	S (6-7)	80±10	min. 240
RNB-M-100	M (7-8)	95±10	min. 240
RNB-L-100	L (8-9)	110±10	min. 240
RNB-XL-100	XL (9-10)	≥ 110	min. 240

THICKNESS

PART OF GLOVE	SINGLE WALL (mm)
finger (13mm from the tip)	0,08±0,01
palm (in the middle part)	0,06±0,01
cuff	0,05±0,01

PHYSICAL PROPERTIES

PARAMETER	BEFORE AGING	AFTER AGING
force at break (N)	min. 6,0	min. 6,0

PACKAGING

	number of pieces	packaging material	packaging dimensions
intermediate packaging	100 pcs	flat cardboard - a cardboard box with a perforation to open, CMYK printing	20x11x6cm
bulk packaging	10 x 100 pcs	carton - corrugated cardboard with printing	31,5x23x21cm

STORAGE CONDITIONS

temperature:	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.	

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Page 1/2

MEDICAL DEVICE / PERSONAL PROTECTIVE EQUIPMENT DATA:

CATALOGUE NUMBER	RNB-XS-100, RNB-S-100, RNB-M-100, RNB-L-100, RNB-XL-100		
MANUFACTURER			
CLASSIFICATION	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		
METHOD OF STERILIZATION	N/A / non-sterile	CODE OF GENERIC DEVICE GROUP ACCORDING TO UMDNS	20932
PERFORMANCE CHARACTERISTICS	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		
CURRENT TECHNICAL STANDARDS ARE APPLICABLE TO THE DEVICE	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		

TECHNICAL DATA:

RAW MATERIALS	100% nitrile (acrylonitrile butadiene)
WEIGHT	3.0 ± 0.2g
COLOUR	blue
FEATURES	<ul style="list-style-type: none"> ▪ cuff: beaded ▪ powder free, the content of powder residue below 2 mg per glove ▪ AQL: 1.0 ▪ texture at the fingertips ▪ internal surface: chlorinated ▪ shape: ambidextrous, fitting to the right and left hand ▪ single-use
SIZES	XS, S, M, L, XL
SHELF LIFE	3 years

EU Type-Examination Certificate

Certificate number: 2777/10648-04/E09-01

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:

Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:	Description:
RNBC03XS - RNBC03XL RNBM03XS - RNBM03XL RNBL03XS - RNBL03XL RNBH03XS - RNBH03XL RNB03XS - RNB03XL FMLRNB03XS - FMLRNB03XL RNBHS03XS - RNBHS03XL RNBS03XS - RNBS03XL RNBSC03XS - RNBSC03XL RNB-XS-RNB-XL RNBR03XS - RNBR03XL	Nitrile examination powder free gloves available in: Black, White, Red, Pink, Blue, Light Purple, Green, Forest Green, Cool Blue, Cornflower Blue, Violet Blue, Marlin Blue, Sky Blue, Dodger Blue, Pearlescent Pink, Harmony Blue, Avocado.

Sizes:	Classification:												
6 (XS) – 10 (XL)	<table><thead><tr><th>EN ISO 374-1:2016/Type B</th><th>Level</th><th>EN374-4:2013</th></tr></thead><tbody><tr><td>37% Formaldehyde</td><td>6</td><td>3.1%</td></tr><tr><td>40% Sodium Hydroxide</td><td>6</td><td>-25.6%</td></tr><tr><td>30% Hydrogen Peroxide</td><td>2</td><td>17.0%</td></tr></tbody></table>	EN ISO 374-1:2016/Type B	Level	EN374-4:2013	37% Formaldehyde	6	3.1%	40% Sodium Hydroxide	6	-25.6%	30% Hydrogen Peroxide	2	17.0%
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EN ISO 374-5:2016													
Resistance to Bacteria and Fungi	Pass												
Resistance to Virus	Pass												

Standards/Technical specifications applied:
EN 420: 2003+A1: 2009; EN ISO 374-1:2016; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHM0265112/1749/EN/A, CHM0265112/1749/EN/B, CHM0265112/1749/SPT, CHM0272621/1826/JS,
CHM0275215/1836/LH, CHM0275215/1836/LH/E, CHM0275215/1836/LH/D, CHM0275215/1836/LH/A/Final
TUV: 7191143339-CHM16-01-RC

Signed on behalf of SATRA:



Hannah Coe



Quincey Brown

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