

easyCARE nitrile basic

Nitrile examination gloves, powder-free

TD-49

Attachment No. 3
point 2 pp. 2.3

Revision I
2021.04.01

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MANUFACTURER:

ADDRESS:

PRODUCT CHARACTERISTICS:

- made of synthetic rubber, which is free from latex and the proteins it contains. This has a positive effect on the working 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: purple blue
- Cuff: beaded
- Powder: powder free; the content of powder residue below 2 mg per glove
- AQL: 1.5
- 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, tested for the penetration of chemicals according to EN ISO 374-1 (type C) 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: S-XL



SIZE AND REFERENCE

CATALOGUE NUMBER	SIZE	INTERMEDIATE PACKAGING	BULK PACKAGING
RNBB-S-100	S	100 pcs	10 x 100 pcs
RNBB-M-100	M	100 pcs	10 x 100 pcs
RNBB-L-100	L	100 pcs	10 x 100 pcs
RNBB-XL-100	XL	100 pcs	10 x 100 pcs

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<i>MEDICAL DEVICE / PERSONAL PROTECTIVE EQUIPMENT DATA:</i>		
CATALOGUE NUMBER	RNBB-S-100, RNBB-M-100, RNBB-L-100, RNBB-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	

<i>TECHNICAL DATA:</i>	
RAW MATERIALS	100% nitrile (acrylonitrile butadiene)
WEIGHT	3.5 ± 0.2g
COLOUR	purple blue
FEATURES	<ul style="list-style-type: none"> ▪ straight cuff with rolled edge ▪ powder free, the content of powder residue below 2 mg per glove ▪ AQL: 1.5 ▪ texture at the fingertips ▪ internal surface: chlorinated ▪ shape: ambidextrous, fitting to the right and left hand ▪ single-use
SIZES	S, M, L, XL
SHELF LIFE	5 years

Technical data sheet

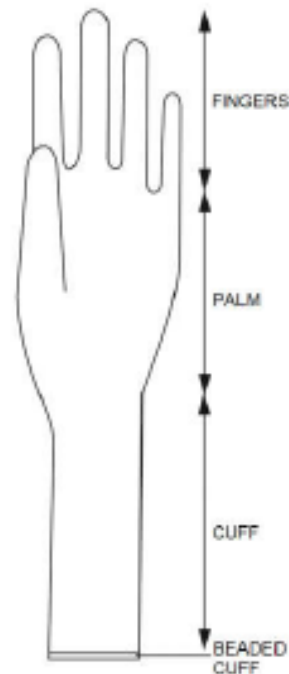
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TECHNICAL DRAWING



DETAILED DIMENSIONS / SPECIFICATION

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

THICKNESS

PART OF GLOVE	SINGLE WALL (mm)
finger (13mm from the tip)	0,10±0,01
palm (in the middle part)	0,07±0,01
cuff	0,06±0,01

PHYSICAL PROPERTIES

PARAMETER	BEFORE AGING	AFTER AGING
force at break (N)	min. 6.0	min. 6.0

PACKAGING

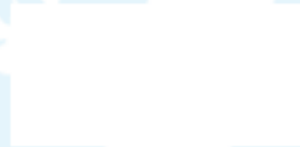
	number of pieces	packaging material	packaging dimensions
intermediate packaging	100 pcs	flat cardboard - a cardboard box with a perforation to open, CMYK printing	20x11x6cm
bulk packaging	10 x 100 pcs	carton - corrugated cardboard with printing	31,5x23x21cm

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.	



Issued to:



Notified Body: 2777

SATRA customer number: P0832

EU Type-Examination Certificate

Certificate number: 2777/12322-02/E10-01

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:

easyCARE nitrile

Description:

Five fingered blue powder free nitrile examination gloves.

Sizes: 6 (XS) -10 (XL)

Classification:

EN ISO 374-1: 2016 /Type C n-heptane (J) 40% Sodium hydroxide (K)	Level	EN 374-4:2013 % Degradation
	1	43
	6	3.5

EN ISO 374-5: 2016 Protection against Bacteria and fungi Protection against viruses	Level
	Pass
	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: PRC0253480/1702/SPT, PRC0253480/1702/EN/A, PRC0253480/1702/EN/B, PRC0253480/1702/EN/D, PRC0253480/1702/EN/E, PRC0253480/1702/EN/G, PRC0253480/1702/EN/I, CHM0282156/1910/JG

Signed on behalf of SATRA:

Gabriela Zajac

Quincey Brown

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