

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:

RNBC03XS - RNBC03XL
RNBM03XS - RNBM03XL
RNBL03XS - RNBL03XL
RNBH03XS - RNBH03XL
RNB03XS - RNB03XL
FMLRNB03XS - FMLRNB03XL
RNBHS03XS - RNBHS03XL
RNBS03XS - RNBS03XL
RNBSC03XS - RNBSC03XL
RNB-XS-RNB-XL
RNBR03XS - RNBR03XL

Description:

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:

6 (XS) – 10 (XL)

Classification:

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%

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

Date of issue: 12/07/2019**Expiry date:** 25/06/2023

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity.

Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.



easyCARE nitrile

Nitrile examination gloves, powder-free

TD-49

Attachment No. 3
point 2 pp. 2.3

Revision II
2020.04.01

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MANUFACTURER: ZARYS International Group sp. z o.o. sp.k.

ADDRESS: ul. Pod Borem 18, 41-808 Zabrze, Poland, phone +48 32 376 07 00-02, fax. +48 32 370 38 08

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 200pcs in colour-coded boxes for size recognition
- Shelf life:** 3 years
- Size:** XS-XL



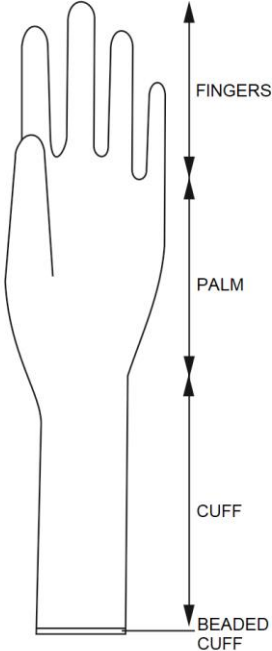
SIZE AND REFERENCE

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
	Nitrile examination gloves, powder-free	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	ZARYS International Group sp. z o.o. sp.k., Poland			
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	<table border="1"> <tr> <td>CODE OF GENERIC DEVICE GROUP ACCORDING TO UMDNS</td> <td>20932</td> </tr> </table>	CODE OF GENERIC DEVICE GROUP ACCORDING TO UMDNS	20932
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

TECHNICAL DRAWING				
	DETAILED DIMENSIONS / SPECIFICATION	REF	SIZE	WIDTH OF PALM (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.			

DEKLARACJA ZGODNOŚCI UE

EU DECLARATION OF CONFORMITY



Wytwórca: **ZARYS International Group spółka z ograniczoną odpowiedzialnością spółka komandytowa**
Manufacturer:
Adres: **ul. Pod Borem 18, 41-808 Zabrze, Poland**
Address: **tel. +48 32 271 69 91, fax +48 32 274 72 84, e-mail: zarys@zarys.pl**

Oświadczamy na wyłączną odpowiedzialność, że wyrób medyczny / Środek Ochrony Indywidualnej:
We declare under our sole responsibility that the medical device / Personal Protective Equipment:

easyCARE nitrile

Rękawice diagnostyczne, nitylowe, bezpudrowe * / Nitrile examination gloves, powder-free * klasy I, reguła 1 / of class I, rule 1

modele / typy: *blue, pink, black*
models / types: rozmiar / size: *od / from XS do / to XL*

* (szczegółowy wykaz wyrobów objętych niniejszą deklaracją zgodności znajduje się w TD-49 Punkt 1 pp. 1.1. zał. nr 5 Identyfikacja wyrobu /
detailed list of products covered by this declaration is available in technical documentation no. TD-49 point 1, subpoint 1.1, appendix no. 5 Identification of the product)

zgodnie z załącznikiem IX Dyrektywy 93/42/EWG zawarty w dokumentacji technicznej TD-49 - dokument zwolnienia do obrotu DZDO-01, który uważa się za część niniejszej deklaracji, spełnia wszystkie stosowne wymagania Dyrektywy 93/42/EWG (procedura oceny zgodności załącznik VII) oraz Ustawy z dnia 20 maja 2010 roku o Wyrobach Medycznych (Dz. U. nr 107, poz. 679 z późniejszymi zmianami).
according to Annex IX of the Directive 93/42/EEC covered by the Technical Files TD-49 - Release Document DZDO-01, which is considered as a part of this declaration meets all applicable provisions of the Directive 93/42/EEC (assessment of the conformity procedure Annex VII) which apply to it as well as of the Act of Medical Devices of 20 May 2010 (Official no. 107, position 679 as amended).

Wyrób wymieniony w niniejszej deklaracji jest zgodny z normami europejskimi EN 455 oraz z wykazem nadzorowanych norm zharmonizowanych wyspecyfikowanym w dokumentacji technicznej wyrobu TD-49.
The device covered by this declaration complies with european standards EN 455 and with the list of supervised harmonised standards specified in the technical documentation of the device TD-49.

Środek Ochrony Indywidualnej wymieniony w niniejszej deklaracji jest zgodny z przepisami Rozporządzenia Parlamentu Europejskiego i Rady (UE) 2016/425 z dnia 9 marca 2016 r. w sprawie środków ochrony indywidualnej oraz uchylecia dyrektywy Rady 89/686/EWG (Kategoria III) oraz z normami europejskimi EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018, EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016.

The Personal Protective Equipment covered by this declaration is in conformity with the provision of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (Category III) and with the european standards EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018, EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016.

Jednostka notyfikowana SATRA Technology Europe Limited (2777) przeprowadziła badanie typu UE (Moduł B) i wydała certyfikat badania typu o numerze 2777/10648-04/E09-01.

The notified body SATRA Technology Europe Limited (2777) performed the EU type-examination (Module B) and issued the EU type-examination certificate no. 2777/10648-04/E09-01.

ŚOI podlega procedurze oceny zgodności z typem w oparciu o wewnętrzną kontrolę produkcji oraz nadzorowane kontrole produktu w losowych odstępach czasu (Moduł C2) pod nadzorem jednostki notyfikowanej SATRA Technology Europe Limited (2777).

The PPE is subject to the conformity assessment procedure conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body SATRA Technology Europe Limited (2777).

Podpisano w imieniu Wytwórcy / Signed for and on behalf of Manufacturer:

PRODUCT MANAGER
ZARYS International Group sp. z o.o. sp.k.

Daniel Kandora

(podpis / signature)

imię i nazwisko / name: Daniel Kandora
stanowisko / position: Product Manager

Miejsce i data wydania / Place and date of issue:
Zabrze, 29.10.2019

Wydanie / Edition: II

DOKUMENTACJA TECHNICZNA / TECHNICAL DOCUMENTATION

TD-49

Identyfikacja wyrobu / Identification of the product

Punkt 1 pp. 1.1 Zał. nr 5 / Point 1, subpoint 1.1, appendix no.5

RĘKAWICE DIAGNOSTYCZNE / EXAMINATION GLOVES				
REF	Nazwa marketingowa/ Brand name	Opis wyrobu	Product description	Rozmiar/ Size
RNBR03XS	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	XS
RNBR03S	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	S
RNBR03M	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	M
RNBR03L	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	L
RNBR03XL	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	XL
RNBC03XS	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	XS
RNBC03S	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	S
RNBC03M	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	M
RNBC03L	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	L
RNBC03XL	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	XL
RNB07XS	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	XS
RNB07S	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	S
RNB07M	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	M
RNB07L	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	L
RNB07XL	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	XL
RNB08XS	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	XS
RNB08S	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	S
RNB08M	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	M
RNB08L	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	L
RNB08XL	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	XL
RNB-XS-100	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	XS
RNB-S-100	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	S
RNB-M-100	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	M
RNB-L-100	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	L
RNB-XL-100	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	XL
RNB-XS-200	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	XS
RNB-S-200	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	S
RNB-M-200	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	M
RNB-L-200	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	L
RNB-XL-200	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Examination gloves, nitrile, powder-free, non-sterile	XL

PRODUCT MANAGER
 ZARYS International Group sp. z o.o. spk
 Daniel Kandora