



# easyCARE nitrile

## Nitrile examination gloves, powder-free, non-sterile

TD-49-I.2.c-2.1.1

revision 9

date: 2021-05-10

amendment of: 2025-11-20

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

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**CLASSIFICATION**Class I medical device compliant with Medical Devices Regulation (EU) 2017/745 (MDR)  
Personal Protective Equipment Category III according to PPE Regulation (EU) 2016/425

The information provided by the manufacturer with the product meets the requirements of Annex I to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 and of point 1.4 of Annex II to Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016

**INTENDED PURPOSE**

- the device is intended for patient diagnostics, providing a barrier to the transmission of microorganisms between the operator and the patient, minimizing the risk of cross-contamination

**FEATURES**

- raw material:** 100% nitrile (acrylonitrile butadiene)
- colour:** blue
- cuff:** beaded
- powder:** powder-free, the content of powder residue below 2mg per glove
- AQL:** 1,0
- internal surface:** chlorinated and polymerized
- outer surface:** polymerized, micro-textured throughout the glove with additional texture at the fingertips
- compliance with the standards:** EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN ISO 13485:2016, EN ISO 13485:2016/A11:2021, EN ISO 9001:2015, EN ISO 9001:2015/A1:2024, EN ISO 14001:2015, EN ISO 14001:2015/A1:2024, EN ISO 14971:2019, EN ISO 14971:2019/A11:2021, EN 62366-1:2015, EN 62366-1:2015/A1:2020, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 10993-1:2020, EN ISO 10993-5:2009/A11:2025, EN ISO 10993-10:2023, EN ISO 10993-23:2021, EN ISO 11737-1:2018, EN ISO 11737-1:2018/A1:2021, ASTM F1671, ASTM D6978, ASTM F739, EN ISO 21420:2020, EN ISO 21420:2020/A1:2024, EN ISO 374-1:2016, EN ISO 374-1:2016/A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016, ASTM D6319
- allowed for contact with food:** in accordance with Regulation (EC) 1935/2004 and Commission Regulation (EC) 10/2011
- intermediate packaging:** 100 pcs or 200 pcs with a colour-coded packaging for easy size recognition
- size:** XS-XL
- single-use**
- non-sterile**
- shelf life:** 5 years



| CATALOGUE NUMBER | SIZE | INTERMEDIATE PACKAGING | BULK PACKAGING |
|------------------|------|------------------------|----------------|
| RNBXS10001       | XS   | 100 pcs                | 10 x 100 pcs   |
| RNBS10001        | S    | 100 pcs                | 10 x 100 pcs   |
| RNBM10001        | M    | 100 pcs                | 10 x 100 pcs   |
| RNBL10001        | L    | 100 pcs                | 10 x 100 pcs   |
| RNBXL10001       | XL   | 100 pcs                | 10 x 100 pcs   |
| CATALOGUE NUMBER | SIZE | INTERMEDIATE PACKAGING | BULK PACKAGING |
| RNBXS20001       | XS   | 200 pcs                | 10 x 200 pcs   |
| RNBS20001        | S    | 200 pcs                | 10 x 200 pcs   |

Marketing material intended for the health care professionals.

Prepared by: A.S. – Quality Manager Bu ZARYS International Group sp. z o.o. sp.k.

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|  | <b>easyCARE nitrile</b><br><b>Nitrile examination gloves, powder-free, non-sterile</b> | TD-49-I.2.c-2.1.1        |
|                                                                                   |                                                                                        | revision 9               |
|                                                                                   |                                                                                        | date: 2021-05-10         |
|                                                                                   |                                                                                        | amendment of: 2025-11-20 |

|            |    |         |              |
|------------|----|---------|--------------|
| RNBM20001  | M  | 200 pcs | 10 x 200 pcs |
| RNBL20001  | L  | 200 pcs | 10 x 200 pcs |
| RNBXL20001 | XL | 200 pcs | 10 x 200 pcs |