



# easyCARE nitrile

## Nitrile examination gloves, powder-free

TD-49-I.2.c-2.1.1

revision 5

date: 2022-08-01

amendment of: 2025-01-20

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

ADDRESS: ul. Pod Borem 18, 41-808 Zabrze, Poland; T: +48 32 376 07 00-02,06 F: +48 32 370 38 08; www.zarys.com

### 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

### 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 + A1:2022, EN 455-2:2024, EN 455-3:2015, EN 455-4:2009, EN ISO 13485:2016 + EN ISO 13485:2016/A11:2021, 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, EN ISO 10993-10:2013, EN ISO 10993-23:2021, EN ISO 11737-1:2018 + EN ISO 11737-1:2018/A1:2021, EN ISO 374-1:2016 + EN ISO 374-1:2016/A1:2018, EN ISO 374-2:2019, EN ISO 21420:2020+A1:2024, EN 16523-1:2015 + A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016, ASTM F1671, ASTM D6978, ASTM D6319
- allowed for contact with food:** in accordance with Regulation (EC) 1935/2004 and Commission Regulation (EC) 10/2011
- quality assurance system:** manufacturing process in accordance with EN ISO 9001 and EN ISO 13485
- 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 | TRANSPORT 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 | TRANSPORT PACKAGING |
| RNBXS20001       | XS   | 200 pcs                | 10 x 200 pcs        |
| RNBS20001        | S    | 200 pcs                | 10 x 200 pcs        |
| RNBM20001        | M    | 200 pcs                | 10 x 200 pcs        |
| RNBL20001        | L    | 200 pcs                | 10 x 200 pcs        |
| RNBXL20001       | XL   | 200 pcs                | 10 x 200 pcs        |

Marketing material intended for the health care professionals.

Prepared by: A.S. – Quality and Regulatory Compliance Specialist ZARYS International Group sp. z o.o. sp.k.

page 1 / 1

No part of this document may be changed or copied without the permission of ZARYS International Group sp. z o.o. sp.k.

rev.2022.01