ZARYS	easyCARE nitrile flex Nitrile examination gloves, powder-free, non-sterile (white)	TD-49-I.2.c-2.2.2 revision 3 date: 2025-06-02 amendment of: 2025-09-30

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**: white
- **cuff:** beaded
- **powder:** powder-free, the content of powder residue below 2mg per glove
- **AQL:** 1,0
- **internal surface**: chlorinated
- **outer surface**: additional texture on 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, 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, 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 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
RNBWXS10003	XS	100 pcs	10 x 100 pcs
RNBWS10003	S	100 pcs	10 x 100 pcs
RNBWM10003	M	100 pcs	10 x 100 pcs
RNBWL10003	L	100 pcs	10 x 100 pcs
RNBWXL10003	XL	100 pcs	10 x 100 pcs

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