



easyCARE nitrile

Nitrile examination gloves, powder-free

TD-49-I.2.c-2.1.1

revision 5

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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

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.

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