ZARYS	easyCARE nitrile black Nitrile examination gloves, powder-free	TD-49-I.2.c-2.1.2 revision 3 date: 2022-11-29 amendment of: 2023-02-14

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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:** black
- **cuff:** beaded
- **powder:** powder free, the content of powder residue below 2mg per glove
- **AQL:** 1,0
- **internal surface:** chlorinated
- **compliance with the standards**: EN 455-1:2020, EN 455-2:2015, 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 11737-1:2018, EN 21420:2020-09, EN ISO 374-1:2016+A1:2018, EN 374-2:2014, EN 16523-1:2015+A1:2018, EN 374-4:2013, EN ISO 374-5:2016, ASTM F1671
- **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 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
RNBCXS10001	XS	100 pcs	10 x 100 pcs
RNBCS10001	S	100 pcs	10 x 100 pcs
RNBCM10001	M	100 pcs	10 x 100 pcs
RNBCL10001	L	100 pcs	10 x 100 pcs
RNBCXL10001	XL	100 pcs	10 x 100 pcs

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