



easyCARE vinyl PF

Vinyl examination gloves, powder-free

TD-49-I.2.c-3.2

revision 3

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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% polyvinyl chloride
- colour:** transparent white
- cuff:** beaded
- powder:** powder free, the content of powder residue below 2mg per glove
- AQL:** $\leq 1,5$
- internal surface:** powder-free
- outer surface:** smooth
- compliance with the standards:** EN 455-1:2020+A1:2022, 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 10993-23:2013, EN ISO 11737-1:2018, ASTM D5250, EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2014, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, 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
RWBXS10001	XS	100 pcs	10 x 100 pcs
RWBS10001	S	100 pcs	10 x 100 pcs
RWBM10001	M	100 pcs	10 x 100 pcs
RWBL10001	L	100 pcs	10 x 100 pcs
RWBXL10001	XL	100 pcs	10 x 100 pcs

- size manufactured to customer's order