



easyCARE vinyl PF

Vinyl powder-free examination gloves, non-sterile

TD-49-I.2.c-3.2

revision 7

date: 2022-11-29

amendment of: 2026-03-02

MANUFACTURER: ZARYS International sp. z o.o.**ADDRESS:** ul. Ziemska 44, 41-803 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

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% polyvinyl chloride
- colour:** transparent white
- cuff:** beaded
- powder:** powder free, the content of powder residue below 2mg per glove
- AQL:** 1.0
- internal surface:** powder-free
- outer surface:** smooth
- compliance with the standards:** EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 455-5:2025, 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 15223-1:2021/A1:2025, EN ISO 20417:2021, EN ISO 10993-1:2020, EN ISO 10993-5:2009/A11:2025, EN ISO 10993-10:2023, EN ISO 10993-23:2021, EN ISO 10993-23:2021/A1:2025, EN ISO 11737-1:2018, EN ISO 11737-1:2018/A1:2021, EN ISO 21420:2020+A1:2024, 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 D5250, ASTM F1671
- 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	BULK 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

Marketing material intended for the health care professionals.

Prepared by: A.S. – Quality Manager BU ZARYS International sp. z o.o.

page 1 / 1

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

rev.04