

EU DECLARATION OF CONFORMITY



manufacturer: **ZARYS International sp. z o.o.**
address: **ul. Ziemska 44, 41-803 Zabrze, Poland**
contact: **tel. +48 32 271 69 91, fax +48 32 274 72 84,
e-mail: zarys@zarys.pl, website: www.zarys.com**
SRN: **PL-MF-000000410**

We declare under our sole responsibility that a medical device/personal protective equipment:

easyCARE nitrile Nitrile examination gloves, powder-free, non-sterile

colour: **blue**

sizes*: **from XS to XL**

(*detailed list of products covered by this declaration is available in document TD-49-I.1.1.b-2.1.1 – Identification – Annex 1)

classification:

- medical device: **class I, rule 5** (in accordance with Annex VIII of Regulation (EU) 2017/745)
- personal protective equipment: **category III**

Basic UDI-DI: **59079968T01020204LZ**

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.

is in conformity with:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices;
- Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment;
- Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food;
- Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

The medical device described above meets all applicable provisions of the Annex I of Regulation (EU) 2017/745.

Conformity assessment procedure has been performed in accordance with Article 52 (7).

For the personal protective equipment the notified body SATRA Technology Europe Limited (2777) performed the EU type-examination (Module B) and issued the EU type-examination certificate:

notified body: **SATRA Technology Europe Limited Bracetown Business Park,
Clonee, D15 YN2P, Ireland** number: **2777**

certificate no.: **2777/21028-04/E21-01** expiry date: **2027-04-15**

The PPE is subject to the conformity assessment procedure conformity to type based on internal production control plus supervised product checks at random intervals (Module D) under surveillance of the notified body SATRA Technology Europe Limited (2777).

The medical device covered by this declaration complies with 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, ASTM F1671, ASTM D6978, ASTM F739, the personal protective equipment complies with standards: 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.

The device intended for food contact meets the requirements specified in Annex 3.

place and date of issue: **Zabrze, 11.03.2026**
name: **Aleksandra Stec**
position: **Quality Manager BU**

ZARYS International sp. z o.o.

Alec
QUALITY MANAGER BU
Aleksandra Stec

Signature

(on behalf of the President of the Management Board)

GENERALNA NAZWA GRUPY/ GENERAL GROUP NAME: niesterylne rękawice diagnostyczne / non-sterile examination gloves					
REF	nazwa handlowa/ trade name	nazwa wyrobu/ name of device	cechy/ features	rozmiar/ size	
model: easyCARE nitrile					
RNBXS10001	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Nitrile examination gloves, powder-free, non-sterile	niebieskie/blue	XS
RNBS10001	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Nitrile examination gloves, powder-free, non-sterile	niebieskie/blue	S
RNBM10001	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Nitrile examination gloves, powder-free, non-sterile	niebieskie/blue	M
RNBL10001	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Nitrile examination gloves, powder-free, non-sterile	niebieskie/blue	L
RNBXL10001	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Nitrile examination gloves, powder-free, non-sterile	niebieskie/blue	XL
RNBXS20001	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Nitrile examination gloves, powder-free, non-sterile	niebieskie/blue	XS
RNBS20001	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Nitrile examination gloves, powder-free, non-sterile	niebieskie/blue	S
RNBM20001	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Nitrile examination gloves, powder-free, non-sterile	niebieskie/blue	M
RNBL20001	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Nitrile examination gloves, powder-free, non-sterile	niebieskie/blue	L
RNBXL20001	easyCARE nitrile	Rękawice diagnostyczne, nitrylowe, bezpudrowe, niesterylne	Nitrile examination gloves, powder-free, non-sterile	niebieskie/blue	XL