EU DECLARATION OF CONFORMITY

manufacturer: ZARYS International Group sp. z o.o. sp.k.
address: ul. Pod Borem 18, 41-808 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:

mediCARE nitrile - nitrile examination gloves, powder-free

colours*: **pink, lime green**

sizes*: **from XS to XL**

(*detailed list of products covered by this declaration is available in document TD-49-I.1.1.b-2.2 – Identification – Annex 1, batch code - release document DZDO-01– Annex 2)

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,
Co. Meath, D15 YN2P, Ireland
number: **2777**

CE 2777

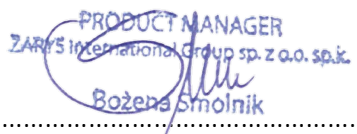
certificate no.: **2777/10648-04/E09-01**
expiry date: **2023-06-25**

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 C2) under surveillance of the notified body SATRA Technology Europe Limited (2777).

The medical device covered by this declaration complies with european 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 11737-1:2018, the personal protective equipment complies with european standards EN 420:2003+A1:2009, 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.

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

place and date of issue: Zabrze, 1.09.2022
name: Bożena Smolnik
position: Product Manager



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signature
(on behalf of the President of the General Partner's Management Board)