

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.pl
registration number: **N/A**

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

easyCARE nitrile - nitrile examination gloves, powder-free

colours*: **blue, pink, black**

sizes*: **from XS to XL**

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

classification:

- medical device: **class I, rule 1**
- personal protective equipment: **category III**

Basic UDI-DI: **59079968T01020204LZ**

is in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 and with Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016.

The medical device meets all applicable provisions of the Annex I to the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017.

Conformity assessment procedure in accordance with Annex IX.

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** number: **2777**
Bracetown Business Park, Clonee,
Co. Meath, D15 YN2P, Ireland



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, 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, EN 374-4:2013, EN ISO 374-5:2016

- a detailed list of supervised standards is specified in the technical documentation TD-49.

place and date of issue: Zabrze, 2020.04.01
name: Daniel Kandora
position: Product Manager

PRODUCT MANAGER
ZARYS International Group sp. z o.o. sp.k.
Daniel Kandora

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