

DECLARATION of CONFORMITY

CE



Manufacturer:

Signed Sp. z o.o.

**ul. Mickiewicza 59
47-253 Cisek, Poland**

We declare under sole responsibility, that following medical device for in vitro diagnostics named **REDTEST PROFESSIONAL**

REF: CV19AGPL - SARS-CoV-2 ANTIGEN RAPID TEST (COVID-19 Ag)
in two variants:

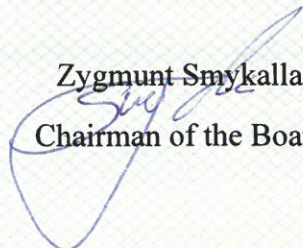
- **throat and nasal secretions**
- **saliva**

GMDN 64912 : SARS-CoV-2 antigen IVD, control

has been classified as medical devices for in vitro diagnostics, other than List A and List B devices, other than self-use devices and other than performance evaluation devices). Described in the Technical Documentation, TD1 meets the essential requirements specified in the IVD Directive 98/79 EC.

Conformity assessment procedure conducted in accordance with Annex 3 to the IVD. The list of harmonized standards are listed in Annex 1.

Cisek, date, 23.12.2020


Zygmunt Smykalla
Chairman of the Board

Annex 1

- **EN ISO 13485:2016**
Medical devices – quality management systems – requirements for regulatory purposes
- **EN ISO 14971:2019**
Medical devices – application of risk management to medical devices
- **EN ISO 15223-1:2016**
Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
- **EN 1041:2008+A1:2013**
Information supplied by the manufacturer of medical devices
- **EN ISO 18113-1:2011**
In vitro diagnostic medical devices – information supplied by the manufacturer (labeling) – Part 1: terms, definitions and general requirements
- **EN ISO 18113-2:2011**
In vitro diagnostic medical devices – information supplied by the manufacturer (labeling) – Part 2: in vitro diagnostic reagents for professional use
- **EN ISO 23640:2015**
In vitro diagnostic medical devices – evaluation of stability of in vitro diagnostic reagents
- **EN 13612:2002/AC: 2002**
Performance evaluation of in vitro diagnostic medical devices
- **EN 62366-1:2015**
Medical devices – Part 1: Application of usability engineering to medical devices