DECLARATION of CONFORMITY

CE IVD

Manufacturer:

Sigmed Sp. z o.o.
ul. Mickiewicza 59
47-253 Cisek, Polska

We declare under sole responsibility, that following medical device named **REDTEST PROFESSIONAL**

REF: CV19ABNPL - SARS-CoV-2 Neutralizing Antibody Rapid Test (COVID-19 Ab)

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 used for the conformity assessment is included in the Technical Documentation.

Cisek, date, 23.12.2020

Zygmunt Smykalla

Chairman of the Board

Sigmed Sp. z o.o.
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