

ROMED HOLLAND

Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: info@romed.nl Website : www.romed.nl
Validity of this Declaration of Conformity until	26 May 2024
Product	Coronavirus Ag Rapid Test Cassette (Swab) Ref: COVID-RAPID-AG, COVID-RAPID-AG1, COVID-RAPID-AG25
Brand	ROMED
Classification	General IVD
UMDNS	17077 Reagents, Viral Serology, Immunodiagnostic
GMDN	64787 (SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid)
EDMS	15-90-90-90-00 Other, Other Infectious Immunology Reagents

We, with sole responsibility in drawing up this Declaration of Conformity, declare that the above mentioned product meets the provisions of the following EC Council Directives and Standards. All supporting documentation is retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives

Directive 98/79/EC of 27 October 1998 concerning medical in vitro diagnostics

Applicable standards

EN 13612:2002, EN ISO 23640:2015, EN 13641:2002, EN 13975:2003, EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016

Wilnis, The Netherlands, 3 November 2020



M.J. van Oostveen
Managing Director