ALGIMED TECHNO

DECLARATION OF CONFORMITY № 018/2022

Manufacturer

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EC REP European Authorized Representative

UAB «V&D group»
51/412 Paneryu St., LT 03160,
Vilnius, Lithuania
Tel.: + 370 (60) 65-31-86
E-mail: logistic@vd-group.lt

Medical device type
Intended purpose device

IN VITRO diagnostic medical device, other diagnostic medical devices
The kit is intended to determine the content of class G immunoglobulins to the RBD site of the glyco-protein S of the SARS-CoV-2 virus in human serum and plasma in order to assess post-infectious or post-vaccination immunity against coronavirus infection (CVI). The kit is intended for in vitro use only.

Product name

Product name	Release form	Catalog number
«ELISA-IgGRBD-SARS-CoV-2»	1 2	E-1-ARBD-96 E-2-ARBD-96

We, the undersigned, hereby declare that the described products meet the essential requirements listed in Directive 98/79/EC of the European Parliament and of the Council dated October 27, 1998. The Technical File required by this Directive is maintained at the Manufacturer's Authorized Representative: UAB "V&D group" 51/412 Paneryu St., LT 03160, Vilnius, Lithuania.

Standards Applied

EN ISO 18113-1:2011; EN ISO 18113-2:2011 (In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements. In vitro diagnostic reagents for professional use); EN ISO 15223-1:2016 (Symbols to be used with medical device labels, labelling and information to be supplied); EN ISO 13485:2016+AC:2016 (Medical devices. Quality management systems. Requirements for regulatory purposes); EN 13612:2002 (Performance evaluation of in vitro diagnostic medical devices); EN 23640:2015 (In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents); EN 13641:2002 (Elimination or reduction of risk of infection related to in vitro diagnostic reagents); EN ISO 14971:2019 (Medical devices. Application of risk management to medical devices).

Licence No. LT/CA01/IVD/018/22

Licensee UAB «V&D group», 51/412 Paneryu St., Vilnius

Start of CE-Marking
18.05.2022

Classification
Other diagnostic medical devices (All devises except Annex II and shelf-testing devices)

Conformity Assessment Procedure
Annex III
of the Directive 98/79/EC
(not including section 6)

Director
Algimed Techno LLC
(Minsk, Belarus)

Vladislav Liutynski

Date: 18.05.2022