Letter of Authorization

To ECHIPAMED PLUS SRL

We, Nanjing Vazyme Medical Technology Co.,Ltd, is engaged as a registered high-tech enterprise in the production of medical diagnostic products in accordance with the relevant laws of China. We hereby permit ECHIPAMED PLUS SRL established in accordance with the laws of Moldova with a principal place of business at str. Valea Trandafirilor 24 "B", of. 80 MD-2001, Chisinau Republic of Moldova as a non-exclusive distributor to sell our

1. 2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit
2. FastPure Viral DNA/RNA Mini Kit
3. Virus Sample Stabilizer
4. Disposable Swab
5. Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)

in the Moldova .

The authorized distributor and we are independent legal entities, so we do not assume any corresponding liabilities for specific business and related behaviors of the authorized distributor.

This authorization is hereby valid from 2020.11.25 to 2021.11.25 . Notwithstanding the foregoing, if the parties do not sign any agreement that the essential is distribution agreement before 2020.12.15 , this authorization shall automatically become invalid.

Nanjing Vazyme Medical Technology Co.,Ltd

Date: 2020.11.25

Digitally signed by Iurchevici Valeriu
Date: 2020.11.25 19:01:02 EET
Reason: MoldSign Signature
Location: Moldova

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 003027 0001 Rev. 01

Holder of Certificate: **Nanjing Vazyme Medical Technology Co.,Ltd.**
F1-F3, Building C2
Red Maple Park of Technological Industry
State Economy & Technology Development Zone
210038 Nanjing
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Nanjing Vazyme Medical Technology Co.,Ltd.
F1-F3, Building C2, Red Maple Park of Technological Industry,
State Economy & Technology Development Zone, 210038
Nanjing, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In-vitro Diagnostic Test Kits based on Latex Particle-enhanced Turbidimetric Immunoassay, Quantum Dot Immunofluorescence, Rapid test for the detection of SARS-COV-2 infection marker, Fluorescence Immunity Analyzer and Specific Protein Analyzer.**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH20128103

Valid from: 2020-04-30
Valid until: 2021-05-08

Date, 2020-04-30

Christoph Dicks
Head of Certification/Notified Body

TÜV®

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Obelis
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER
Obelis
SINCE 1988

CERTIFICATE OF IVD NOTIFICATION

Ref. No. : AF 0047-2020

Belgium

Order No. : GR 9973- 2020

Date: 27/10/2020

This is to certify that, according to the Council Directive 98/79/EC, Obelis s.a. (O.E.A.R.C.) performed a ll notification duties and responsibilities as the European Authorized Representative (EC REP) of:

name: Nanjing Vazyme Medical Technology Co., Ltd

Address: Floor 1-3, Building C2, Red Maple Park of Technological Industry, Kechuang Road, Economy & Technology Development Zone, Nanjing, Chi na

as stipulated and demanded by the aforementioned directive.

The Manufacturer declares that the IVD device complIES with the Directive including all essential requireme nts. The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations accordi ng to the 98/79/EC Directive - article 10 requirements including the EC Declaration of Conformity confirmi ng that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable r equirements of the European Council Directive 98/79/EC The notification of the following In-Vitro Diagnos tic medical device has been completed by Obelis s.a. (O.E.A.R.C.) on the 26/10/2020 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

In-vitro diagnostic medical devices: Please See Annex A - List of Devices (1 page, 1 Device)

As of the 27/10/2020, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore: - Is required to affix the CE marking on this device; - Place this device in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with De cision 2010/227/EU).

Obelis s.a. - O.E.A.R.C.

Mr. G. Elkayam CEO
Obelis sa

EAAR

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

** This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon ter mination of the EAR agreement.

* This is not a CE mark and is only provided as a template for informational purposes.

CE

Registered Address: Bd. Général Wahis 53- 1030 Brussels I Registered Office Address: Bd Brand Whitlock 30, B-1200 Brussels - Belgium
T: + 32 (0) 2 732 5954 I F: + 32 (0) 2 732 6003 I Email: mail@obelis.net I Website: www.obelis.net
V3 - ID: 00454716 - 22/02/2019

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TECHNOMED-PLUS" IDNO 1003600077677

Order No.: GR 9973- 2020
Ref No.: AF 0047-2020

Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN/ EDMS Code	Class
1.	C8602C	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)	SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid	The test kit is applicable to detect the antigen of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen in human throat swab, Nasal swab samples.	64787	All others

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturerand under its sole responsibility (IVD 98/79/EC).

Obelis s.a.

Signature: G.ELKAYAM C.E.O.

Stamp:

Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tel. +32 2 732 59 54 - Fax +32 2 732 60 03