E.A.R.-CERTIFICATE

(ART 10.3 of the Directive 98/79/EC on In Vitro Diagnostic)

DATE: 08/06/2020

REF. NO. : DT 9328-2020

ORDER NO. : PV 9286-2020

MANUFACTURER:

Reszon Diagnostics
International Sdn. Bhd.
Revongen Corporation Center,
Level 17, Top Glove Tower, No.
16, Persiaran Setia Dagang,
Setia Alam, Seksyen U13,
40170 Shah Alam, Selangor
Darul Ehsan, Malaysia.

FACILITIES:

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PRODUCT CATEGORIES:

Please See Annex A - List of Devices (2 Devices, 1 Page)

MODELS:

Please See Annex A - List of Devices (2 Devices, 1 Page)

The European Authorized Representative Center Obelis s.a. declares that the aforementioned manufacturer has fulfilled the essential requirement of appointing a European Authorized Representative in accordance with article 10.3 of the Directive 98/79/EC and to the terms and conditions set out in the agreement entered into force on 01/06/2020

G.ELKAYAM C.E.O.

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Mr. G. Elkayam CEO
Obelis sa

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 is not a confirmation of product notification nor an approval to place products on the market.
**This certificate will become void automatically upon termination of the EAR agreement.

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

Order No.: PV 9286-2020
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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	RCV-RD0101	Reszon COVID-19 Rapid IgG/IgM Test	In vitro diagnostic devices	Virology Rapid Test for the serological (IgG/ IgM) detection of COVID-19 infection. It is intended to be used for the detection of SARS-CoV-2 virus infection.	15 70 90 90 00	All others
2	RCV-RD0201	Reszon COVID-19 Rapid Antigen Test	In vitro diagnostic devices	Virology Rapid Test for the antigen detection of COVID-19 infection. It is intended to be used for the detection of SARS-CoV-2 virus infection.	15 70 90 90 00	All others

EUROPEAN AUTHORIZED REPRESENTATIVE CENTER
Obelis SA
SINCE 1988

Obelis s.a.

Date: 08/06/2020
Signature and *Stamp:*

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