E.A.R.-CERTIFICATE

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

REF. NO. : KS 0478-2020

ORDER NO. : DK 0276-2020

DATE: 30/12/2020

MANUFACTURER: Shinjin Medics Inc., A302-2, A401-2, A401-3, Ilsan-Techno Town, 138, Ilsan-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do 10442, Republic of Korea

FACILITIES: Shinjin Medics Inc., A302-2, A401-2, A401-3, Ilsan-Techno Town, 138, Ilsan-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do 10442, Republic of Korea

PRODUCT CATEGORIES: Please See Annex A - List of Devices (3 Devices, 1 Page)

MODELS: Please See Annex A - List of Devices (3 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 01/08/2014.*

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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.

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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 / GIVD Code	Class
1.	PF09	DIAKEY COVID-19 IgM/IgG Rapid Test	DIAKEY COVID-19 IgM/IgG Rapid Test	Solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum, plasma.	15.04.80.19	Others
2.	MF01	DIAKEY REALcheck COVID-19 (nCOV) Detection Kit	DIAKEY REALcheck COVID-19 (nCOV) Detection Kit	For the qualitative detection of nucleic acid from the COVID-19 in sputum, nasopharyngeal and oropharyngeal swabs specimens collected from individuals with signs and symptoms of infection who are suspected of COVID-19.	15.04.40.19	Others
3.	PF10	DIAKEY COVID-19 Ag Rapid Test	DIAKEY COVID-19 Ag Rapid Test	Immunochromatographic assay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider.	15.04.80.19	Others

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