CERTIFICATE
Of CE (MDD) NOTIFICATION

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/0312

Certificate No.: CMC/CE/2020/0312

PRODUCTS DETAIL IN ANNEX I (1 page)

MANUFACTURER BY COMPANY:

Goldsite Diagnostics Inc.

Address : No. 103C, 503C & 504D, Technology Building & No. 3A & 4A, Technology Building Annex, Zhaoshang Sub-District, Nanshan District, Shenzhen, China, 518067

The Manufacturer declares that comply with the applicable essential requirements of the Council Directive 98/79/EC and Regulation (EU) 2017/746 concerning in vitro diagnostic medical devices.

The manufacturer has provided CMC Medical Devices S.L. with all appropriate declarations as per the European Council Directive 98/79/EEC including EC Declaration of Conformity (according to Annex III) confirming that their class I medical devices, as stipulated here below, are fulfilling the applicable requirements of the European council Directive 98/79/EEC.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix to each medical device, of the above reference models, the CE Marking according to this example:

CE IVD

CMC Medical Devices has performed all notification duties and responsibilities as the European Authorized representative of Goldsite Diagnostics Inc. therefore may place these devices in the European community territory as long as the Manufacturer will continue complying with the hereabove mentioned requirements.

Issued on: 12/03/2020

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ANNEX I:

Product Name	Model	Classification	Conformity assessment route
Instrument	**Cat. No.**	Non listed devices of IVDD 98/79/EC	Directive 98/79/EC, article 9, annex III: others
Time-resolved Fluoroimmunoassay Analyzer	GT-100		
Reagent Description	**Cat. No.**		
GT-100SARS-CoV-2 IgG/IgM Kit	GT122025		