



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex III (6)

(Devices for self-testing)

No. V9 114344 0001 Rev. 00

Manufacturer:

BIOSYNEX SWISS SA

Route de Rossemaison 100
2800 Delémont
SWITZERLAND

Product:

In Vitro diagnostic devices for self testing

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex III (6). The design of the devices conforms to the requirements of this Directive. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V9 114344 0001 Rev. 00

Report No.:

713253475

Valid from:

2022-05-03

Valid until:

2024-05-26

Date,

2022-05-03

Christoph Dicks
Head of Certification/Notified Body



EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex III (6)

(Devices for self-testing)

No. V9 114344 0001 Rev. 00

Model(s):

BIOSYNEX AUTOTEST COVID-19
BIOSYNEX AUTOTEST ANTIGENIQUE COVID-19 Ag

Facility(ies):

BIOSYNEX SWISS SA
Route de Rossemaison 100, 2800 Delémont, SWITZERLAND

BIOSYNEX S.A.
22 boulevard Sébastien Brant, 67400 ILLKIRCH-
GRAFFENSTADEN, FRANCE

BIOSYNEX SWISS SA
Rue de Romont 29-31, 1700 Fribourg, SWITZERLAND

Parameters:

Model Name:

Model Nr.:

BIOSYNEX AUTOTEST COVID-19	859081
BIOSYNEX AUTOTEST COVID-19	859082
BIOSYNEX AUTOTEST ANTIGENIQUE COVID-19 Ag	859256
BIOSYNEX AUTOTEST ANTIGENIQUE COVID-19 Ag	859257
BIOSYNEX AUTOTEST ANTIGENIQUE COVID-19 Ag	859258
BIOSYNEX AUTOTEST ANTIGENIQUE COVID-19 Ag	859261
BIOSYNEX AUTOTEST ANTIGENIQUE COVID-19 Ag	859262
BIOSYNEX AUTOTEST ANTIGENIQUE COVID-19 Ag	859263
BIOSYNEX AUTOTEST ANTIGENIQUE COVID-19 Ag	859385