ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 101277 0001 Rev. 00

Manufacturer:

BIOSYNEX SWISS SA
Rue de Romont 29-31
1700 Fribourg
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 101277 0001 Rev. 00

Report No.: 713187335

Valid from: 2020-10-23
Valid until: 2024-05-26

Date, 2020-10-23

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

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Model(s): **BIOSYNEX AUTOTEST COVID - 19**

Facility(ies):

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

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

Parameters:

Model name:	Model number:
BIOSYNEX AUTOTEST COVID-19	859081
BIOSYNEX AUTOTEST COVID-19	859082

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