



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. 01**

**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. 01](http://www.tuvsud.com/ps-cert?q=cert:V9_101277_0001_Rev.01)

**Report No.:**

713209301

**Valid from:**

2021-07-13

**Valid until:**

2024-05-26

**Date,**

2021-07-13

Christoph Dicks  
Head of Certification/Notified Body



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 Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex III (6)  
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**No. V9 101277 0001 Rev. 01**

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

**Facility(ies):** BIOSYNEX SWISS SA  
 Rue de Romont 29-31, 1700 Fribourg, SWITZERLAND  
 BIOSYNEX S.A.  
 22 boulevard Sébastien Brant, 67400 ILLKIRCH-  
 GRAFFENSTADEN, FRANCE

<b>Parameters:</b>	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