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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Digitally signed by Bolea Petru
Date: 2022.07.14 14:34:51 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service

Certificate

No. Q5 002187 0005 Rev. 01

Holder of Certificate: **BIOSYNEX S.A.**

BIOSYNEX

22 boulevard Sébastien Brant
67400 ILLKIRCH-GRAFFENSTADEN
FRANCE

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production, distribution and servicing of rapid in vitro diagnostic tests and instruments and distribution of active medical devices for diagnosis**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 002187 0005 Rev. 01

Report No.: 713193456

Valid from: 2020-12-23
Valid until: 2023-12-22

Date, 2020-12-15

Christoph Dicks
Head of Certification/Notified Body

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

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TÜV SÜD Product Service

Certificate

No. Q5 002187 0005 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

Design and development, production, distribution and servicing of rapid in vitro diagnostic tests and instruments and distribution of active medical devices for diagnosis

BIOSYNEX S.A.
12 rue Ettore Bugatti, Eckbolsheim-CS28006, 67038 STRASBOURG CEDEX, FRANCE

Site representation

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

Site representation

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