

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

Add value. Inspire trust.

To whom it may concern

Munich, 2023-02-14 Order No.: 713293712

Confirmation concerning EC Certificate No. V1 002187 0006 Rev. 05

We confirm that the following certificate:

V1 002187 0006 Rev. 05 (valid until 2025-05-26)

issued to the following legal medical device manufacturer:

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

covers the Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4,6) (List A and B and devices for self-testing) with the scope:

Products for determination of infection markers and in vitro diagnostic devices for self testing

and the following devices:

Device Name:			DefNe
English	French	Hungarian	Ref No.:
BIOSYNEX Pregnancy Test 8 days	BIOSYNEX Test de grossesse 8 jours	BIOSYNEX TERHESSÉGI teszt 8 NAPOS	859948
BIOSYNEX Self-test Gluten	BIOSYNEX Autotest Glu- ten	BIOSYNEX Autoteszt GLUTÉN	859947



With this letter we confirm that the above-mentioned devices are covered by a quality assurance system that has been established by the manufacturer and is certified by the notified body TÜV SÜD Product Service GmbH.

After issuing the declaration of conformity in accordance with the medical device directive 98/79/EC by the manufacturer, the above-mentioned medical devices can be labelled with CE mark (CE 0123) and placed on the market in the European Economic Area.

The above-mentioned certificate is valid.

Randolf Köhler

TÜV SÜD PRODUCT SERVICE GMBH

Medical Health Services

R. Kohler

Foreign Affairs

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