

March 04th 2021

STATEMENT OF EQUIVALENCE

We, **BIOSYNEX SWISS S.A., Rue de Romont 29-31, 1700 Fribourg - SWITZERLAND**, legal manufacturer of the below products hereby declare that:

BIOSYNEX COVID-19 Ag BSS, reference SW40006

And

BIOSYNEX COVID-19 Ag Antigenic Self-testing Kit,

references 859256/859257/859258/859261/859262/859263

Are the same products (same manufacturing process).

Only the final packaging and labelling of the product are different since there are intended for different markets (professional and lay-users respectively).

Validation of the professional version BIOSYNEX COVID-19 Ag BSS, reference SW40006 is therefore transferable to the self-testing version offered by BIOSYNEX in the context of the special authorization in the Netherlands.

Thank you for your understanding.

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