CORIS BioConcept	EC Declaration of Conformity according to Annex III of the IVDD

This is to certify that following IVD product:

Product name	Product codes
COVID-19 Ag Respi-Strip	C-1023 C-1323

are manufactured and sold by

Coris BioConcept
Science Park CREALYS
Rue Jean Sonet 4A
5032 Gembloux
BELGIUM

This product:

1. Belong to the Class "Others/General" as they are not for self-testing and do not belong to List A or List B of Annex II of IVDD (98/79 EC).
2. Comply with all Essential Requirements (Annex I) of the IVDD (98/79 EC)
3. This compliance has been properly documented using a checklist created from Annexes I and III of the IVDD, linked to all supporting Technical Documentation. This documentation included both product specific and process (Quality System) specific documents.
4. Have a Quality System in place based on ISO 13485.
5. This Declaration is issued by Coris BioConcept and has an unlimited time validity.
6. This Declaration of Conformity is signed below, certifying these requirements have been met and documented.

For Coris BioConcept, made in Gembloux the 24th of March 2020

Thierry LECLIPTEUX, PhD
CEO
Coris BioConcept