EC Declaration of Conformity according to Annex III of the IVDD

This is to certify that following IVD products:

- **Rota-Strip (C-1001)**
- **Combi-Strip & Combi K-SeT (C-1004; K-1204; K-1504)**
- **RSV Respi-Strip & RSV K-SeT (C-1006; K-1206; K-1506)**
- **Adeno Respi-Strip & Adeno Respi K-SeT (C-1009; K-1209; K-1509)**
- **Influ A+B K-SeT (K-1212; K-1512)**
- **Giardia-Strip & Giardia K-SeT (C-1013; K-1513)**
- **Legionella *K*-SeT (K-1215; K-1515)**
- **GastroVir K-SeT (K-1516)**
- **Crypto/Giardia Duo-Strip (C-1018)**
- **Pylori-Strip & Pylori K-SeT (C-1019; K-1519)**
- **Clostridium K-SeT (K-1220; K-1520)**
- **COVID-19 Ag Respi-Strip (C-1023, C-1123, C-1223, C-1323)**
- **COVID-19 Ag *K*-SeT (K-1525)**
- **Proguanil / Malarone™-Strip; Proguanil-Strip (C-10T1; C-40T1)**
- **Mefloquine / Lariam™-Strip; Mefloquine-Strip (C-10T2; C-40T2)**
- **HAT Sero K-SeT (K-12S2; K-15S2)**
- **OXA-48 K-SeT (K-15R1)**
- **RESIST-3 O.O.K. K-SeT (K-15R4)**
- **RESIST-3 O.K.N. K-SeT (K-15R5)**
- **RESIST-4 O.K.N.V. (K-15R8)**
- **OXA-23 K-SeT (K-15R7)**
- **RESIST-5 O.O.K.N.V. (K-15R9)**
- **IMP *K*-SeT (K-15R10)**
- **O.K.N.V.I. RESIST-5 (K-15R11)**
- **RESIST ACINETO (K-15R13)**
- **RESIST CTX-M (K-15R14)**
- **BL-RED 25 (RED-0001)**
- **SARS-CoV-2 RT-LAMP (L-0001)**
- **FLU A & FLU B RT-LAMP (L-0002)**
- **Rotavirus Positive Control (P-1001)**
- **Adenovirus Positive Control (P-1002)**
- **RSV Positive Control (P-1006)**
- **Influenza A Positive Control (P-1010)**
- **Giardia Positive Control (P-1013)**
- **Pylori Positive Control (P-1019)**
- **Legionella Positive Control (P-1015)**
- **C difficile Positive Control (P-1020)**
- **RESIST penta O.K.N.V.I. control (P-10R11)**
- **OXA-163 Positive Control (P-10R4-1)**
- **OXA-23 Positive Control (P-10R7)**
- **COVID-19 Ag Positive Control (P-1023)**
- **Negative Control (CTR-1000)**

are manufactured and sold by **Coris BioConcept**
Science Park CREALYS
Rue Jean Sonet 4A - 5032 Gembloux - BELGIUM

These products:

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 Annex 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 ISO 13485
5. This Declaration is issued by Coris BioConcept and has 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 25th of May, 2022

DocuSigned by:
Leclipteux
4CD9C99D3A3C4D5...

T. Leclipteux
C.E.O

DocuSigned by:
Coralie Misson
D0352556EF0343C...

C. Misson
QA Manager