

This is to certify that following IVD products:

- Rota-Strip (C-1001)
- Adeno-Strip (C-1002)
- 40/41 Adeno-Strip (C-1003)
- Combi-Strip & Combi K-SeT (C-1004; K-1204; K-1504)
- Crypto-Strip (C-1005)
- 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)
- O157 Coli-Strip (C-1011)
- Infl A+B K-SeT (K-1212; K-1512)
- Giardia-Strip & Giardia K-SeT (C-1013; K-1213; K-1513)
- Legionella K-SeT (K-1215; K-1515)
- GastroVir-Strip & GastroVir K-SeT (C-1016; K-1216; K-1516)
- Crypto/Giardia Duo-Strip (C-1018)
- Pylori-Strip & Pylori K-SeT (C-1019; K-1219; K-1519)
- C.diff-Strip & Clostridium K-SeT (C-1020; K-1220; K-1520)
- Strep-A Respi-Strip (C-1022)
- P. aeruginosa mexQ-TesT (C-3806)
- 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)
- KPC K-SeT (K-15R2)
- 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)
- BL-RED 25 (RED-0001)
- Adenovirus Positive Control (C-1082)
- RSV Positive Control (C-1086)
- Influenza A Positive Control (C-1090)
- E. coli O157 Positive Control (C-1091)
- Infl A&B Control Test (C-1092)
- Giardia Lamblia Control Test (C-1093)
- Pylori Positive Control (C-1099)
- Strep-A Positive Control (P-1022)
- 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 21st of March, 2019

T. Leclipteux
C.E.O



C. Misson
QA Manager

