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# EC Declaration of Conformity according to Annex III of the IVDD

This is to certify that following IVD products:

| Product name | Product code |
|---|---|
| Rota-Strip | C-1001 |
| Rota Uni-Strip | C-1501 |
| Combi-Strip | C-1004 |
| Combi K-SeT | K-1204 |
| Combi K-SeT | K-1504 |
| RSV Respi-Strip | C-1006 |
| RSV K-SeT | K-1206 |
| RSV K-SeT | K-1506 |
| Adeno Respi-Strip | C-1009 |
| Adeno Respi K-SeT | K-1209 |
| Adeno Respi K-SeT | K-1509 |
| Influ A+B K-SeT | K-1212 |
| Influ A+B K-SeT | K-1512 |
| Giardia Strip | C-1013 |
| Giardia K-SeT | K-1513 |
| Legionella K-SeT | K-1215 |
| Legionella K-SeT | K-1515 |
| GastroVir K-SeT | K-1516 |
| Crypto/Giardia Duo-Strip | C-1018 |
| Pylori-Strip | C-1019 |
| Pylori K-SeT | K-1519 |
| Clostridium K-SeT | K-1220 |
| Clostridium K-SeT | K-1520 |
| COVID-19 Ag Respi-Strip | C-1023 |
| COVID-19 Ag Respi-Strip | C-1123 |
| COVID-19 Ag Respi-Strip | C-1223 |
| COVID-19 Ag Respi-Strip | C-1323 |
| COVID-19 Sero NP/RBD | K-1224 |

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| | |
|---|---|
| COVID-19 Ag K-SeT | K-1525 |
| HAT Sero K-SeT | K-12S2 |
| HAT Sero K-SeT | K-15S2 |
| OXA-48 K-SeT | K-15R1 |
| RESIST-3 O.O.K. K-SeT | K-15R4 |
| RESIST-3 O.O.K. K-SeT | K-15R4/XBRI |
| RESIST-3 O.O.K. K-SeT | K-11R4/XBRI |
| RESIST-3 O.K.N. K-SeT | K-15R5 |
| OXA-23 K-SeT | K-15R7 |
| O.K.N.V.I. RESIST-5 | K-15R11 |
| O.K.N.V.I. RESIST-5 | K-15R11/XBRIT |
| O.K.N.V.I. RESIST-5 | K-11R11/XBRIT |
| RESIST ACINETO | K-15R13 |
| RESIST CTX-M | K-15R14 |
| IMP K-SeT | K-15R10 |
| BL-RED 25 | RED-0001 |
| SARS-CoV-2 RT-LAMP | L-0001 |
| Flu A & FLU B RT-LAMP | L-0002 |
| Negative control | CTR-1000 |
| 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 |
| Legionella Positive Control | P-1015 |
| Pylori Positive Control | P-1019 |
| 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 |
| Proguanil / Malarone – Strip | C-10T1 |
| Mefloquine / Lariam - Strip | C-10T2 |

are manufactured and sold by

**Coris BioConcept**
**CREALYS Science Park**
**Rue Guillaume Fouquet, 11**
**5032 Gembloux, BELGIUM**

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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 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 09th of May 2023

DocuSigned by:
Thierry Leclipteux
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Thierry LECLIPTEUX, PhD
CEO
Coris BioConcept