

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

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

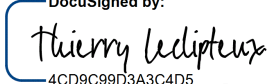
Coris BioConcept
CREALYS Science Park
Rue Guillaume Fouquet, 11
5032 Gembloux, BELGIUM



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:

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Thierry LECLIPTEUX, PhD
CEO
Coris BioConcept