



WETENSCHAPPELIJK INSTITUUT
VOLKSGEZONDHEID
INSTITUT SCIENTIFIQUE
DE SANTÉ PUBLIQUE

CORIS BioConcept
Mr Leclipteux
Parc Scientifique CREALYS
Rue Jean Sonet 4
B-5032 GEMBLOUX

Quality of Medical Laboratories

date: 28/03/2017
your ref.:
our ref.: WIV/IVD/303-16
annex(es):

contact: Jeroen Poels
tel.: + 32 2 642 53 94
fax: + 32 2 642 56 45
e-mail: jeroen.poels@wiv-isp.be
IVD@wiv-isp.be

SUBJECT: IVD Notification

Dear Mr Leclipteux,

Please find enclosed the original notification form for the CE marked in vitro diagnostic medical devices, notified to the Belgian Competent Authority. This notification form is an acknowledgement of your declaration that the in vitro diagnostic medical devices, mentioned hereunder, fully comply with the Directive 98/79 of the European Parliament and of the Council. Be aware that it is an offence to place on the market non-complying devices bearing the CE marking. This form does not represent an accreditation or approval by the Belgian Competent Authority.

Please inform us of any changes (change of company information, change of address, significant change of product, change of certificate) and of the discontinuation of the product.

For the products listed hereunder, the Belgian Competent Authority for in vitro diagnostic medical devices has entered the data referred to in point (a), and if applicable point (b), of Article 12(1) of Directive 98/79/EC into Eudamed in accordance with the Annex to Decision 2010/227/EU of 19 April 2010 on the European Databank on Medical Devices (Eudamed).

Sincerely yours,

Jeroen Poels
IVD Competent Authority



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IVD@wiv-isp.be

Re: notification of IVD products according to the directive 98/79

Competent Authority: BE/CA02

Manufacturer: CORIS BioConcept,
Parc Scientifique CREALYS
Rue Jean Sonet 4
B-5032 GEMBLOUX
BELGIUM

Date of registration: 24/09/2016

Type of IVD: Instruments/ reagents for professional use

IVD	GMDN code	Registration number
Adeno-Strip (C-1002/C-1003)	41274	BE-CA02-001-01
Crypto-Strip (C-1005)	30675	BE-CA02-002-01
Combi-Strip (C-1004)	38442	BE-CA02-003-01
Rota-Strip (C-1001)	30815	BE-CA02-004-01
RSV Respi-Strip (C-1006)	30814	BE-CA02-005-02
Adeno Respi-Strip (C-1009)	41274	BE-CA02-093-02
Influ-A Respi-Strip (C-1010)	30813	BE-CA02-094-02
Adeno Uni-Strip (C-1502)	41274	BE-CA02-675-03
Influ-A Respi Uni-Strip (C-1510)	30813	BE-CA02-676-03
40/41 Adeno Uni-Strip (C-1503)	41274	BE-CA02-677-03
Crypto Uni-Strip (C-1505)	30675	BE-CA02-678-03
Combi Uni-Strip (C-1504)	38442	BE-CA02-679-03
Rota Uni-Strip (C-1501)	30815	BE-CA02-680-03
RSV Uni-Strip (C-1006)	30814	BE-CA02-681-03
Adeno Respi Uni-Strip (C-1509)	41274	BE-CA02-682-03
O157 Coli-Strip (C-1011)	37727	BE-CA02-683-03
O157 Coli Uni-Strip (C-1511)	37727	BE-CA02-684-03
Giardia-Strip & Giardia Uni-Strip (C-1013/C-1513)	36173	BE-CA02-838-03

RSV Positive Control (C-1086)	42248	BE-CA02-338-04
Influ A+B Respi Strip (C-1012)	30813	BE-CA02-019-05
Influ A+B Uni-Strip (C-1512)	30813	BE-CA02-020-05
Gastro Vir-Strip (C-1016)	30815	BE-CA02-016-06
Gastro Vir Uni-Strip (C-1516)	41274	
Rota-CIT (C-1201)	30815	BE-CA02-257-06
Adeno-CIT (C-1202)	38442	BE-CA02-258-06
Combi-CIT (C-1204)	38442	BE-CA02-259-06
Crypto-CIT (C-1205)	30675	BE-CA02-260-06
RSV-Respi-CIT (C-1206)	30814	BE-CA02-261-06
Adeno-Respi-CIT (C-1209)	38442	BE-CA02-262-06
Influ A Respi-CIT (C-1210)	30813	BE-CA02-263-06
O157 Coli-CIT (C-1211)	37727	BE-CA02-264-06
Influ A & B Respi-CIT (C-1212)	30813	BE-CA02-265-06
Giardia-CIT (C-1213)	36173	BE-CA02-266-06
GastroVir ^{COLOR} -CIT (C-1216)	38442	BE-CA02-267-06
Adeno 40/41 CIT (C-1203)	38442	BE-CA02-268-06
Control Test Infl A & B (C-1092)	41758	BE-CA02-026-07
Control Test Adeno 40/41(C-1083)	41273	BE-CA02-027-07
Control Test Giardia (C-1093)	38442	BE-CA02-028-07
Influenza A positive control (C-1090)	41758	BE-CA02-040-07
Crypto/Giardia Duo-Strip, Crypto/Giardia Uni-Strip, Crypto/Giardia-CIT	30675 36173	BE-CA02-001-08
Leishmania OligoC- Test (C-3405 (20 tests), C-3705 (10 tests))	38442	BE-CA02-172-08
T. cruzi OligoC- Test (C-3404 (20 tests), C-3704 (10 tests))	38442	BE-CA02-173-08
Pylori-Strip (C-1019 (25 tests)), Pylori Uni-Strip (C-1519 (10 single tests)), Pylori -CIT (C-1219 (20 single tests))	30825	BE-CA02-174-08
Negative Control (CTR-1000)	38442	BE-CA02-175-08
GastroVir Control Test (C-1096)	38442	BE-CA02-297-08
Pylori Positive Control (C-1099)	38442	BE-CA02-298-08
Legionella V-Test (10 tests (C-1815); 20 tests(C-1915))	30692	BE-CA02-299-08
RSV K-SeT (K-1506, K-1206)	49500	BE-CA02-216-10
Combi K-SeT (K-1504, K-1204)	48235	BE-CA02-217-10
Pylori K-SeT (K-1519, K-1219)	30825	BE-CA02-218-10
Adeno Respi K-SeT (K-1509, K-1209)	49856	BE-CA02-268-10
Influ-A K-SeT (K-1510, K-1210)	49150	BE-CA02-269-10
Giardia K-SeT (K-1513, K-1213)	52249	BE-CA02-270-10
P.aeruginosa mexQ-TesT (C-3806)	51266	BE-CA02-271-10
Proguanil / Malarone - Strip (C-10T1), Proguanil - Strip (C-40T1)	38442	BE-CA02-012-11
PG Uni-Strip (C-45T1)	38442	BE-CA02-013-11
Mefloquine / Lariam - Strip (C-10T2), Mefloquine - Strip (C-40T2)	38442	BE-CA02-014-11
MQ Uni-Strip (C-45T2)	38442	BE-CA02-015-11
Clostridium K-SeT (K-1220, K-1520, 56001044, 56001056)	30714	BE-CA02-146-11
GastroVir K-SeT (K-1516, K-1216)	30815	BE-CA02-188-12
C.diff-Strip (C-1020)	30714	BE-CA02-189-12
E.coli O157 Positive Control (C-1091)	44023	BE-CA02-190-12
Legionella Card Ietitest (56001036, 56001048)	30692	BE-CA02-191-12
HAT Sero K-SeT (K-12S2, K-15S2)	38442	BE-CA02-261-12
Influ A+B K-SeT (K-1212, K-1512)	30813	BE-CA02-262-12

Helicobacter pylori Strip letitest (56001033, 56001051)	30825	BE-CA02-263-12
Helicobacter pylori Card letitest (56001034, 56001050, 56102001)	30825	BE-CA02-264-12
Influenza A+B Strip letitest (56001035, 56001047)	30813	BE-CA02-265-12
RSV Strip letitest (56001041, 56001045)	30814	BE-CA02-266-12
RSV Card letitest (56001042, 56001046, 56101003)	30814	BE-CA02-267-12
Legionella GDT letitest (56001037, 56001049)	30692	BE-CA02-268-12
Adenovirus 40/41 Strip letitest (56001027, 56001054)	41274	BE-CA02-269-12
Gastrovir Strip letitest (56001030, 56001055)	30815	BE-CA02-270-12
C. difficile Ag Card letitest (56001044, 56001056)	30714	BE-CA02-271-12
Adeno Respiratory Strip letitest (56001026)	41274	BE-CA02-272-12
Giardia Card letitest (56001032)	36173	BE-CA02-273-12
Giardia Strip letitest (56001031)	36173	BE-CA02-274-12
Cryptosporidium / Giardia Combo Strip letitest (56001029)	30675	BE-CA02-275-12
Cryptosporidium Strip letitest (56001028)	30675	BE-CA02-276-12
Adeno Respiratory Card letitest (56001025)	41274	BE-CA02-109-13
Rotavirus/Adenovirus Combo Strip letitest (56001038)	41274	BE-CA02-110-13
Rotavirus/Adenovirus Combo Card letitest (56001039)	41274	BE-CA02-111-13
Rotavirus Strip letitest (56001040)	30815	BE-CA02-112-13
Influenza A+B Card letitest (56001052, 56101002)	30813	BE-CA02-434-13
Adeno 40 Positive Control (C-1082)	41273	BE-CA02-435-13
Strep-A letitest (56001063)	30710	BE-CA02-150-14
Strep-A Respi-Strip (C-1022)	30710	BE-CA02-199-14
Legionella K-SeT (K-1215, K-1515)	30692	BE-CA02-200-14
OXA-48 K-SeT (K-15R1)	33359	BE-CA02-001-15
STREP-A Positive Control (P-1022)	30710	BE-CA02-002-15
Strep-A Card letitest (56101001)	30710	BE-CA02-054-15
OXA-48 Card letitest (56001065)	33359	BE-CA02-199-15
KPC K-SeT (K-15R2)	33359	BE-CA02-200-15
KPC K-SeT letitest (56001066)	33359	BE-CA02-345-15
NDM K-SeT (K-15R6)	61275	BE-CA02-303-16
RESIST-3 O.O.K. K-SeT (K-15R4)	61275	BE-CA02-304-16
RESIST-3 O.K.N. K-SeT (K-15R5)	61275	BE-CA02-305-16

Jeroen Poels
IVD Competent Authority



This notification contains 3 pages and replaces the certificate issued 17/05/2016.



SGS

Certificate BE03/60023.00

The management system of

Coris BioConcept

Science Park CREALYS - Rue Jean Sonet 4A
5032 Gembloux, Belgium

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016



For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 17 October 2018 until 20 August 2021
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 20 July 2021

Issue 12. Certified since 20 August 2003

Multiple certificates have been issued for this scope

The main certificate is numbered BE03/60023.00

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Expiry date of last certificate: 20 August 2018

End date of last recertification audit: 05 July 2018

Authorised by



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HC SGS 13485 2016 0118 M2

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Certificate BE03/60023.00, continued

Coris BioConcept

ISO 13485:2016
EN ISO 13485:2016



Issue 12

Detailed scope

Design, development, manufacture and distribution of in vitro diagnostic tests for the detection of pathogens in the diagnosis of respiratory, gastric, enteric and parasitic diseases, the detection of resistance to antibiotics and the detection in urine of therapeutics, used for the treatment of these infectious diseases

Additional facilities

**Science Park CREALYS - Rue Jean Sonet, 29
5032 Gembloux, Belgium**



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Page 2 of 2



EC Declaration of Conformity according to Annex III of the IVDD

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)
- 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)
- IMP K-SeT (K-15R10)
- BL-RED 25 (RED-0001)
- Adenovirus Positive Control (C-1082)
- RSV Positive Control (C-1086)
- Influenza A Positive Control (C-1090)
- 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 2nd of October, 2019

T. Leclipteux
C.E.O

C. Misson
QA Manager

