

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



WETENSCHAPPELIJK INSTITUUT
VOLKSGEZONDHEID

INSTITUT SCIENTIFIQUE
DE SANTÉ PUBLIQUE

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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 |

