CORIS BioConcept

Science Park CREALYS
Rue Jean Sonet 4A
5032 - GEMBLOUX - BELGIUM
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e-mail : info@corisbio.com
http://www.corisbio.com

STATEMENT

We, **CORIS BIOCONCEPT** having a registered office at SCIENCE PARK CREALYS, Rue Jean Sonet 4A, 5032 Gembloux, BELGIUM assign SRL Sanmedico, having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as authorized representative in correspondence with the conditions of directive 98/79/EC.

For the purpose of business development and tender participation, We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Gembloux, June 26th, 2019

CORIS BIOCONCEPT
RUE JEAN SONET 4A
BE-5032 GEMBLOUX

Thierry LECLIPTEUX
CEO & CSO

Digitally signed by Rodnițchii Andrei
Date: 2019.09.30 14:01:26 EEST
Reason: MoldSign Signature
Location: Moldova

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

UKAS
MANAGEMENT
SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

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

UKAS MANAGEMENT SYSTEMS
0005

CORIS BioConcept

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)**
- **O157 Coli-Strip (C-1011)**
- **Influ 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)**
- **Influ 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