

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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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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