

Certificate BE21/819944231.00

The management system of

Coris BioConcept

Science Park CREALYS - Rue Jean Sonet 4A
5032 Gemboux, 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 07 April 2021 until 20 August 2021
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 20 August 2003.
Recertification audit due before 20 July 2021.

Multiple certificates have been issued for this scope.
The main certificate is numbered BE21/819944231.00.

This is a multi-site certification.
Additional site details are listed on subsequent pages.

Authorised by



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Accreditation Number

005-QMS
EN ISO/IEC 17021-1:2015

007 QS



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Coris BioConcept

ISO 13485:2016

EN ISO 13485:2016



Issue 1

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.

Distribution of instrument for electrochemical detection to be used with Coris' kit.

Additional facilities

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



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