

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Coris BioConcept
CREALYS Science Park
Rue Guillaume Fouquet, 11
Gembloux
5032
Belgium

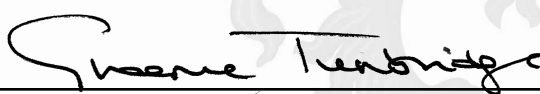
Holds Certificate Number:

MD 800972

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following 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 an instrument for electrochemical detection for use with these tests.

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2024-04-24

Latest Revision Date: 2024-08-01

Effective Date: 2024-08-21

Expiry Date: 2027-08-20

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