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This is to certify that the Management System of:

## Bioanalytic GmbH

Waldmatten 10-13, 79224 Umkirch, Germany

has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 - 00036906

## The scope of this approval is applicable to:

Development, manufacturing and distribution of unsterile in vitro diagnostic reagents for clinical chemistry, haematology and histology / cytology.

LRQA Group Limited, its affiliates and subsidiaries and their respective officers, employees or agents are, individually and collectively, referred to in this clause as 'LRQA'.

This certificate is a continuation of a previous approval from another certification body as follows:

Previous original ISO 13485 approval on 08-DEC-2021, PUG certificate number K12146-20211208-Q-en

## Marta Escudero

Regional Director, Europe

Issued by: LRQA Limited

