

Certificate of Approval

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.

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

Paul Graaf

Area Operations Manager, Europe

Issued by: LRQA Limited

