



# Certificate

No. Q5 084062 0010 Rev. 03

**Holder of Certificate:** **BÜHLMANN Laboratories AG**  
Baselstr. 55  
4124 Schönenbuch  
SWITZERLAND

**Certification Mark:**



**Scope of Certificate:** **Design, development, manufacturing and distribution of in-vitro diagnostic medical devices, in particular reagents for Clinical Chemistry and Immunochemistry, IVD Instruments for Chemistry and Immunochemistry, and IVD Generic use consumables for Sample collection. Provision of distribution services for in-vitro diagnostic medical devices, in particular reagents for Clinical Chemistry, Immunochemistry, Haematology, Microbiology, Infectious diseases and Genetic Testing, IVD Instruments for Chemistry/Immunochemistry, Microbiology, Nucleic Acid Testing, Sample processing Systems and General purpose, IVD Generic use consumables for Sample collection, including the provision of services for IVD Instrument Installation and Instrument Services.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5\\_084062\\_0010\\_Rev.03](http://www.tuvsud.com/ps-cert?q=cert:Q5_084062_0010_Rev.03)

**Report No.:** 713310136

**Valid from:** 2024-05-12

**Valid until:** 2027-05-11

**Date,** 2024-04-26



Christoph Dicks

Head of Certification/Notified Body

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**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):** **BÜHLMANN Laboratories AG**  
Baselstr. 55, 4124 Schönenbuch, SWITZERLAND

Design and development of in-vitro diagnostic medical devices, in particular reagents for Clinical Chemistry and Immunochemistry, IVD Instruments for Chemistry and Immunochemistry, and IVD Generic use consumables for Sample collection.

**BÜHLMANN Laboratories AG**  
Im Kirschgarten 25, 4124 Schönenbuch, SWITZERLAND

Distribution of in-vitro diagnostic medical devices, in particular reagents for Clinical Chemistry and Immunochemistry, IVD Instruments for Chemistry and Immunochemistry, and IVD Generic use consumables for Sample collection. Provision of distribution services for in-vitro diagnostic medical devices, in particular reagents for Clinical Chemistry, Immunochemistry, Haematology, Microbiology, Infectious diseases and Genetic Testing, IVD Instruments for Chemistry/Immunochemistry, Microbiology, Nucleic Acid Testing, Sample processing Systems and General purpose, IVD Generic use consumables for Sample collection, including the provision of services for IVD Instrument Installation and Instrument Services.

**BÜHLMANN Laboratories AG**  
Im Kirschgarten 29, 4124 Schönenbuch, SWITZERLAND

Manufacturing and distribution of in-vitro diagnostic medical devices, in particular reagents for Clinical Chemistry and Immunochemistry, IVD Instruments for Chemistry and Immunochemistry, and IVD Generic use consumables for Sample collection. Provision of distribution services for in-vitro diagnostic medical devices, in particular reagents for Clinical Chemistry, Immunochemistry, Haematology, Microbiology, Infectious diseases and Genetic Testing, IVD Instruments for Chemistry/Immunochemistry, Microbiology, Nucleic Acid Testing, Sample processing Systems and General purpose, IVD Generic use consumables for Sample collection.



Product Service

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## Facility(ies):

### **BÜHLMANN Laboratories AG**

Hagenthalerstrasse 146, 4124 Schönenbuch, SWITZERLAND

Manufacturing of in-vitro diagnostic medical devices, in particular reagents for Clinical Chemistry and Immunochemistry.

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