



America

CERTIFICATE

No. QS6 084062 0011 Rev. 04

Certificate Holder:

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

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

**Australia TGA, Brazil ANVISA, Health Canada, USA FDA.
See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_084062_0011_Rev.04

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID:

F001196

Report No.:

713357132

Effective Date:

2025-05-19

Expiry Date:

2027-06-10

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Date of Issue: 2025-05-27

(Renee Walker)
Director, US Certification Body, MHS

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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada

- Medical Device Regulations – Part 1- SOR 98/282

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

BÜHLMANN Laboratories AG

Baselstr. 55, 4124 Schönenbuch, SWITZERLAND

BÜHLMANN Laboratories AG

Im Kirschgarten 29, 4124 Schönenbuch, SWITZERLAND

BÜHLMANN Laboratories AG

Im Kirschgarten 25, 4124 Schönenbuch, SWITZERLAND

BÜHLMANN Laboratories AG

Hagenthalerstrasse 146, 4124 Schönenbuch, SWITZERLAND

BÜHLMANN Laboratories AG

Libsbachmühleweg 2, 4124 Schönenbuch, SWITZERLAND



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Facility Scopes:

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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

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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

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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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Libsbachmühleweg 2, 4124 Schönenbuch, SWITZERLAND

Management 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

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