



America

# CERTIFICATE

No. QS6 084062 0011 Rev. 02

**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. Validity of this certificate can be obtained by visiting the website [www.tuvsud.com/ps-cert](http://www.tuvsud.com/ps-cert)

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

**REPs Facility ID:** **F001196**

**Effective Date:** **2022-10-18**

**Expiry Date:** **2024-06-10**

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**Date of Issue:** 2022-12-20

( Renee Walker )  
Manager, US Certification Body,  
Medical and Health Services



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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. 16/2013  
 - RDC ANVISA n. 23/2012  
 - RDC ANVISA n. 67/2009

**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

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