



America

CERTIFICATE

No. QS6 084062 0011 Rev. 00

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

Certification Mark:



Scope of Certificate: **Design and Development, Manufacturing and Distribution of In-Vitro Diagnostics including Immunoassays and Clinical Chemistry for Determination of Cellular Allergy, Inflammation and Applications in Neuroimmunology, Chronobiology, Therapeutic Drug Monitoring and Testing of Drugs of Abuse**

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

REPs Facility ID: **F001196**
Effective Date: **2021-06-18**
Expiry Date: **2022-06-10**

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 Date of Issue: 2021-07-13

(Tina Israel)
 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

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Facility Scopes:

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Design and Development, Manufacturing and Distribution of In-Vitro Diagnostics including Immunoassays and Clinical Chemistry for Determination of Cellular Allergy, Inflammation and Applications in Neuroimmunology, Chronobiology, Therapeutic Drug Monitoring and Testing of Drugs of Abuse
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BÜHLMANN Laboratories AG

Im Kirschgarten 29, 4124 Schönenbuch, SWITZERLAND

Manufacturing and Distribution of In-Vitro Diagnostics including Immunoassays and Clinical Chemistry for Determination of Cellular Allergy, Inflammation and Applications in Neuroimmunology, Chronobiology, Therapeutic Drug Monitoring and Testing of Drugs of Abuse
REPs Facility ID: F001196

BÜHLMANN Laboratories AG

Im Kirschgarten 25, 4124 Schönenbuch, SWITZERLAND

Sales of In-Vitro Diagnostics including Immuno-assays and Clinical Chemistry for Determination of Cellular Allergy, Inflammation and Applications in Neuroimmunology, Chronobiology, Therapeutic Drug Monitoring and Testing of Drugs of Abuse
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