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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 004797 0001 Rev. 02

Certificate Holder: **Precision BioLogic, Inc.**
140 Eileen Stubbs Avenue
Dartmouth NS B3B 0A9
CANADA

Certification Mark:

Scope of Certificate: **Design, Development and Manufacture and Distribution of In-Vitro Diagnostic Medical Devices (Controls, Calibrators, Reagents and Kits) used in the Clinical Laboratory Assessment of Blood Analytes and Blood Properties for the Diagnosis of Coagulation Disorders associated with Hemostasis**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, 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 004797 0001 Rev. 02
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F003906**
Report No.: **721001112**
Effective Date: **2024-12-13**
Expiry Date: **2027-12-12**

Date of Issue: 2024-10-07

(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

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):

Precision BioLogic, Inc.
140 Eileen Stubbs Avenue, Dartmouth NS B3B 0A9, CANADA

Precision BioLogic Inc
130 Eileen Stubbs Avenue, Suite 5S (& 26N-Lab), Dartmouth NS B3B 2C4, CANADA

Facility Scopes:

Precision Biologic, Inc.
140 Eileen Stubbs Avenue, Dartmouth NS B3B 0A9, CANADA

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