



CERTIFICATE

No. QS6 068906 0036 Rev. 03

Certificate Holder:

Whip Mix Corporation
361 Farmington Avenue
Louisville KY 40209
USA

Certification Mark:



Scope of Certificate:

Design and Development and Production of Non-Sterile Medical Devices such as 3D Print Resins for 3D Printed Dental Restorations, Articulators and Facebows, Articulating Papers, and Bite Separation Devices for Evaluation of Dental Occlusion;

Distribution of 3D Print Resins, Articulators, Facebows, Articulating Papers, Bite Separation Devices, Dental Polishing Material, and Bite Registration Material;

Service of Articulator and Facebow

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_068906_0036_Rev.03

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

REPs Facility ID:

F007199

Report No.:

0721017243

Effective Date:

2026-08-13

Expiry Date:

2027-07-22

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Date of Issue: 2026-08-19

(Sofia Epshtein Elbrus)

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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):

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