



America

# CERTIFICATE

No. QS6 068906 0036 Rev. 01

**Certificate Holder:** Whip Mix Corporation  
361 Farmington Avenue  
Louisville KY 40217  
USA

**Certification Mark:**



**Scope of Certificate:** Design and Development and Production of Non-Sterile Medical Devices, 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.01](http://www.tuvsud.com/ps-cert?q=cert:QS6_068906_0036_Rev.01)

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

**REPs Facility ID:** F007199  
**Report No.:** 72198284  
**Effective Date:** 2024-08-07  
**Expiry Date:** 2027-07-22

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( Renee Walker )  
Director, US Certification Body, MHS

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<b>Regulatory Requirements:</b>	<b>Audit/Certification Criteria</b>  <b>Australia</b> Therapeutic Goods (Medical Devices) Regulations 2002 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure  <b>Canada</b> - Medical Device Regulations – Part 1- SOR 98/282  <b>United States</b> - 21 CFR Part 803 - 21 CFR Part 806 - 21 CFR Part 807 – Subparts A to D - 21 CFR Part 820
<b>Facility(ies):</b>	<b>Whip Mix Corporation</b> 361 Farmington Avenue, Louisville KY 40217, USA  <b>Whip Mix Corporation</b> 1730 E. Prospect Road, Fort Collins CO 80525, USA
<b>Facility Scopes:</b>	<b>Whip Mix Corporation</b> 361 Farmington Avenue, Louisville KY 40217, USA  Design and Development, Production and Distribution of 3D Print Resins, and Articulating Papers; Distribution of Dental Polishing Material REPs Facility ID: F007199  <b>Whip Mix Corporation</b> 1730 E. Prospect Road, Fort Collins CO 80525, USA  Design and Development, Production and Distribution of Articulators, Facebows, and Bite Separation Devices; Distribution of Bite Registration Material; Service of Articulator and Facebow REPs Facility ID: F007200

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( Renee Walker )  
 Director, US Certification Body, MHS