ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
Medical Device Single Audit Program

America

CERTIFICATE

No. QS6 068906 0036 Rev. 02

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 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. 02
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F007199**
Report No.: **0721017243**
Effective Date: **2026-02-23**
Expiry Date: **2027-07-22**

Date of Issue: 2026-03-23

(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): **Whip Mix Corporation**
361 Farmington Avenue, Louisville KY 40217, USA

Facility Scopes: 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;

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