



America

# CERTIFICATE

No. QS6 101492 0003 Rev. 03

**Certificate Holder:**  
**sagemax®****Sagemax Bioceramics Inc**  
34210 9th Avenue South, Suite 118  
Federal Way WA 98003  
USA**Certification Mark:****Scope of Certificate:****Design, Manufacture and Distribution  
of Dental Products for Indirect Restoration,  
Veneering and Prosthetics****Standard(s):****ISO 13485:2016****Regulatory Authority(ies):****Australia TGA, Brazil ANVISA, Health Canada,  
Japan MHLW / PMDA, 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 101492 0003 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:QS6_101492_0003_Rev.03)

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

**REPs Facility ID:****F002631****Report No.:****713338837****Effective Date:****2025-05-03****Expiry Date:****2028-05-02**

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( 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

### Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices  
- RDC ANVISA n. 551/2021  
- RDC ANVISA n. 67/2009 - Vigilance

### Canada

- Medical Device Regulations – Part 1- SOR 98/282

### Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)  
- Japan PMD Act (as applicable)

### United States

- 21 CFR Part 803  
- 21 CFR Part 806  
- 21 CFR Part 807 – Subparts A to D  
- 21 CFR Part 820

## Facility(ies):

### Sagemax Bioceramics Inc

34210 9th Avenue South, Suite 118, Federal Way WA 98003, USA

## Facility Scopes:

Manufacture and Distribution of Dental Products for Indirect Restoration, Veneering and Prosthetics  
REPs Facility ID: F002631

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