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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 101492 0003 Rev. 02

Certificate Holder:
sagemax®

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

Certification Mark:

TÜV SÜD ISO 13485

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, USA FDA, MHLW / PMDA. 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. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F002631**

Effective Date: **2022-05-23**

Expiry Date: **2025-05-02**

Date of Issue: 2022-05-27

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services

TÜV®

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuvsud.com

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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 101492 0003 Rev. 02

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. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

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

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

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

Date of Issue: 2022-05-27

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services