



America

CERTIFICATE

No. QS6 019612 0063 Rev. 00

Certificate Holder:



AMANNGIRRBACH

Amann GIRRACH AG
Herrschaftswiesen 1
6842 Koblach
AUSTRIA

Certification Mark:



Scope of Certificate:

Design, Development, Production and Distribution
of Dental Materials for the Production of Dental
Prosthesis for Dental Laboratories, Dentists and
Dental Clinics

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 <https://www.tuev-sued.de/product-testing/certificates>

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

DUNS No:

30-070-8950

Effective Date:

2019-04-15

Expiry Date:

2022-04-14

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Date of Issue: 2019-04-16

(Arie Henkin)
Manager, Certification Body MHS

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Regulatory Requirements: Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil

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

Canada

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

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan

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

Facility(ies):

Amann Girrbach AG
Herrschaftswiesen 1, 6842 Koblach, AUSTRIA

Amann Girrbach GmbH
Dürrenweg 40, 75177 Pforzheim, GERMANY

Amann Girrbach AG
Schweizerstrasse 96, 6830 Rankweil, AUSTRIA

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Facility Scopes:

Amann Girrbach AG

Herrschaftswiesen 1, 6842 Koblach, AUSTRIA

Design, Development, Production and Distribution of Dental Materials for the Production of Dental Prosthesis for Dental Laboratories, Dentists and Dental Clinics

DUNS No: 30-070-8950

Amann Girrbach GmbH

Dürrenweg 40, 75177 Pforzheim, GERMANY

Production and Distribution of Dental Materials for the Production of Dental Prosthesis for Dental Laboratories, Dentists and Dental Clinics

DUNS No: 33-356-0196

Amann Girrbach AG

Schweizerstrasse 96, 6830 Rankweil, AUSTRIA

Production and Distribution of Dental Materials for the Production of Dental Prosthesis for Dental Laboratories, Dentists and Dental Clinics

DUNS No: 30-056-1783

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