



America

CERTIFICATE

No. QS6 105007 0001 Rev. 00

Certificate Holder: Juvaplus S.A.
Rue du pré 10
2114 Fleurier
SWITZERLAND

Certification Mark:



Scope of Certificate: Design and Development, Manufacture, Servicing and Distribution of Powered Injection System for the area of Aesthetic Medicine and Dental Anesthetic

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Australia TGA, 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.tuvsud.com/en/services/product-certification/ps-cert>

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

DUNS No: 48-602-6102

Effective Date: 2020-03-23

Expiry Date: 2023-03-22

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(Tina Israel)
Manager, US Certification Body,
Medical and Health Services

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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

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):

Juvaplus S.A.
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