




America

# CERTIFICATE

No. QS6 063179 0068 Rev. 01

**Certificate Holder:** **STORZ & BICKEL GMBH**  
 In Grubenäcker 5-9  
 78532 Tuttlingen  
 GERMANY

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Manufacturing and Distribution of Vaporizer Systems for Release of Cannabinoids out of Cannabis Blossoms (Cannabis Flos), Cannabis Extracts or Pure Cannabinoids for Medical Purpose such as Chronic Pain, Spasticity and Muscle Spasms, Anorexia and Chachexia, Nausea and Emesis**

**Standard(s):** **ISO 13485:2016**

**Regulatory Authority(ies):** **Australia TGA, Health Canada. 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](http://www.tuvsud.com/ps-cert)  
 TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**DUNS No:** **33-225-1177**

**Effective Date:** **2020-08-19**

**Expiry Date:** **2021-12-02**

Page 1 of 2  
**Date of Issue:** 2020-08-26

( 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

**Facility(ies):**

STORZ & BICKEL GMBH  
 In Grubenäcker 5-9, 78532 Tuttlingen, GERMANY

**Facility Scopes:**

Design and Development, Manufacturing and Distribution of Vaporizer Systems for Release of Cannabinoids out of Cannabis Blossoms (Cannabis Flos), Cannabis Extracts or Pure Cannabinoids for Medical Purpose such as Chronic Pain, Spasticity and Muscle Spasms, Anorexia and Chachexia, Nausea and Emesis  
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Page 2 of 2

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