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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 063179 0068 Rev. 02

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

Certification Mark:

TÜV SÜD ISO 13485

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, 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. 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: **F001736**

Effective Date: **2021-12-14**

Expiry Date: **2024-12-13**

Date of Issue: 2021-12-20

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services

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C E R T I F I C A T E

No. QS6 063179 0068 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

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

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

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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