



MDSAP

Medical Device Single Audit Program



America

CERTIFICATE

No. QS6 130477 0002 Rev. 00

Certificate Holder: ECO PHYSICS AG
Bubikonerstr. 45
8635 Dürnten
SWITZERLAND

Certification Mark:



Scope of Certificate: Design and Development, Manufacture, and Distribution of Gas Analyzers for Medical Diagnostics for the area of Pneumology

Standard(s): ISO 13485:2016

Regulatory Authority(ies): 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. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_130477_0002_Rev_00

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

REPs Facility ID: F008204
Report No.: 713367383
Effective Date: 2025-10-14
Expiry Date: 2028-10-13

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Date of Issue: 2025-10-24

(Renee Walker)
Director, US Certification Body, MHS



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Regulatory Requirements: Audit/Certification Criteria

United States

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

Facility(ies):

ECO PHYSICS AG

Bubikonerstr. 45, 8635 Dürnten, SWITZERLAND

Facility Scopes:

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(Renee Walker)
Director, US Certification Body, MHS