



America

CERTIFICATE

No. QS6 115802 0003 Rev. 01

Certificate Holder:

FotoFinder Systems GmbH
Industriestr. 12
84364 Bad Birnbach
GERMANY

Certification Mark:



Scope of Certificate:

**Design and Development, Manufacture, Distribution,
Installation and Service of Skin Imaging Systems for Digital
Dermoscopy, Trichoscopy and Total Body Mapping**

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

**Australia TGA, Brazil ANVISA, 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. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6 115802 0003 Rev. 01

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

REPs Facility ID:

F006669

Report No.:

713367925

Effective Date:

2025-06-29

Expiry Date:

2028-06-28

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Date of Issue: 2025-06-30

(Renee Walker)
Director, US Certification Body, MHS

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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

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

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):

FotoFinder Systems GmbH

Industriestr. 12, 84364 Bad Birnbach, GERMANY

FotoFinder Systems GmbH

Industriestr. 11a, 84364 Bad Birnbach, GERMANY

Facility Scopes:

FotoFinder Systems GmbH

Industriestr. 12, 84364 Bad Birnbach, GERMANY

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