



America

CERTIFICATE

No. QS6 101310 0006 Rev. 02

Certificate Holder: **BrightInsight, Inc.**
333W San Carlos Street
RiverPark Tower, 5th Floor
San Jose CA 95110
USA

Certification Mark:



Scope of Certificate: **Design and Development, Production, Distribution and Service of Mobile Applications and Cloud-Based Software for Managing Medical Data**

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_101310_0006_Rev.02

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

REPs Facility ID: **F004353**
Report No.: **721001543**
Effective Date: **2024-10-09**
Expiry Date: **2026-01-23**

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Date of Issue: 2024-10-11

(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):

BrightInsight, Inc.

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Facility Scopes:

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