Certificate of Registration

Certificate number
14279.250713

File number
A28987

Initial issue date
2022-07-13

Cycle start date
2025-07-13

Effective date
2025-07-13

Expiry date
2028-07-12

Accumedix, Inc

800 Liberty Drive
Libertyville, Illinois 60048 UNITED STATES

Facility ID: F005971

UL LLC, UL Solutions medical and regulatory services issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016
EN ISO 13485:2016/A11:2021

with additional regulatory requirements listed on the final page of this certificate.

Production, packaging and distribution of general non-active implantable and non-implantable medical devices; active devices for wound care; non-active and active dental devices; and general active non-implantable medical devices.

Certificate with Addendum(s) totals 3 pages.

Authorized by:

Paul Daysh
Operations manager – Medical Regulatory

Check certificate status: here

This quality system registration is included in UL's Product iQ directory and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown. By issuance of this certificate, the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferrable and remains the property of UL Solutions.

UL LLC, UL Solutions medical regulatory services is an MDSAP Recognized Auditing Organization

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

Addendum 1

Site	Company Name	Location	Performing
1-1	Accumedix, Inc	800 Liberty Drive Libertyville Illinois 60048 UNITED STATES Facility ID: **F005971**	Contract Manufacturer

Additional Regulatory Requirements

Accumedix, Inc
800 Liberty Drive
Libertyville, Illinois 60048 UNITED STATES

Facility ID: F005971

United States:
- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 821 (where applicable)