

Merit

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This certificate is granted and awarded by the authority of the MedAccred Management Council to:

Benchmark Electronics, Inc.

*4065 Theurer Blvd
Winona, MN 55987
United States*

This certificate demonstrates conformance and recognition of accreditation for specific services, as listed in www.eAuditNet.com on the Qualified Manufacturers List (QML), to the revision in effect at the time of the audit for:

Printed Circuit Board Assemblies

Certificate Number: 156012004143
Expiration Date: 28 February 2023
Accreditation Length: 18 Months

A handwritten signature in black ink, appearing to read "D. Schutt", written over a horizontal line.

David L. Schutt, PhD
President

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SCOPE OF ACCREDITATION

Printed Circuit Board Assemblies

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This certificate expiration is updated based on periodic audits. The current expiration date and scope of accreditation are listed at: www.eAuditNet.com - Online QML (Qualified Manufacturer Listing).

In recognition of the successful completion of the PRI evaluation process, accreditation is granted to this facility to perform the following:

AC8120 Rev A - MedAccred Audit Criteria for Printed Circuit Board Assemblies (to be used on audits on/after 6 November 2016)

- 04.0 General
- 05.0 Process Validation
- 06.0 Medical Record Keeping
 - 06.1 Device Master Record (DMR)
 - 06.2 Device History Record (DHR)
 - 06.3 Product Traceability
- 07.0 Foreign Object Damage and Foreign Object Debris (FOD) Prevention
- 08.0 Electrostatic Discharge (ESD) Management
- 09.0 Calibration
- 10.0 Preventive Maintenance
- 12.0 Purchasing and Authentic Component Assurance
- 13.0 Process Control
- 14.0 CAD/CAM Data
- 15.0 Receipt, Inspection & Control of Incoming Material
- 16.0 Storage and Handling of Received Materials
- 17.0 Component Programming
 - 17.2 PCBA–Level Component Programming
- 18.0 Electronic Component Preparation
- 19.0 Stencil Printing
- 20.0 Component Placement
 - 20.1 Manual
 - 20.3 Automated Part Placement
 - 20.4 Build Through / Build Short
 - 20.5 Through Hole Component Lead Trimming
- 21.0 In–Process Placement Verification / Inspection
 - 21.1 General
 - 21.2 Visual

- 21.3 Automated Optical Inspection (AOI)
- 21.4 X-Ray
- 22.0 Assembly Soldering Processes
 - 22.1 Reflow Soldering
 - 22.2 Wave Soldering
 - 22.3 Selective Soldering
 - 22.4 Hand Soldering
- 23.0 Secondary Assembly
 - 23.1 Mechanical Part Installation
 - 23.2 Wire Cutting & Stripping
 - 23.3 Jumper Wire Installation
 - 23.5 Compliant Pin (Press Fit) Connector Installation
- 24.0 PCBA Cleaning Process and Control
- 26.0 Adhesive Bonding
- 27.0 Assembly Testing
 - 27.3 Environmental Stress Screening or Highly Accelerated Stress Screening (ESS / HASS)
 - 27.4 In-Circuit Testing
 - 27.5 Flying Probe Testing
 - 27.6 Boundary Scan Testing
 - 27.7 Manual Bench Testing
 - 27.8 Functional Testing
- 28.0 Final Acceptance Inspection
- 29.0 Rework
- 30.0 Storage, Handling & Packaging of Finished Goods