

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

Benchmark Electronics, Inc.

3535 Technology Dr NW Rochester, MN 55901 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: 87782001942 Expiration Date: 31 July 2020 Accreditation Length: 12 Months

Michael J. Hayward

Vice President and Chief Operating Officer



SCOPE OF ACCREDITATION

Printed Circuit Board Assemblies

Benchmark Electronics, Inc. 3535 Technology Dr NW Rochester, MN 55901

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

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- 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
 - 23.5 Compliant Pin (Press Fit) Connector Installation
- 24.0 PCBA Cleaning Process and Control
- 25.0 Coating and Encapsulation
 - 25.1 Coating and Encapsulation Process
- 25.2 Coating and Encapsulation Inspection (Mandatory if 25.0 Coating and Encapsulation is checked)
- 27.0 Assembly Testing
 - 27.4 In-Circuit Testing
 - 27.5 Flying Probe 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

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