

SCOPE OF ACCREDITATION

Printed Board Assemblies

Grayhill Inc. 4800 Vernon Ave McCook, IL 60540

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 B - MedAccred Audit Criteria for Printed Circuit Board Assemblies (to be used on

audits on/AFTER 05-Mar-2023)

04.0 General

- 05.0 Process Validation
- 06.0 Medical Record Keeping
 - 6.1 Device Master Record (DMR)
 - 6.2 Device History Record (DHR)
 - 6.3 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
- **19.0 Stencil Printing**
- 20.0 Component Placement
 - 20.1 Manual
 - 20.3 Automated Part Placement
- 21.0 In-Process Placement Verification / Inspection
 - 21.1 General
 - 21.2 Visual
 - 21.3 Automated Optical Inspection (AOI)
- 22.0 Assembly Soldering Processes
 - 22.1 Reflow Soldering
 - 22.3 Selective Soldering
 - 22.4 Hand Soldering

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- 23.0 Secondary Assembly
- 23.1 Mechanical Part Installation
- 24.0 PCBA Cleaning Process and Control
- 27.0 Assembly Testing
 - 27.4 In-Circuit Testing
 - 27.8 Functional Testing
- 28.0 Final Acceptance Inspection
- 29.0 Rework
- 30.0 Storage, Handling & Packaging of Finished Goods