

## SCOPE OF ACCREDITATION

### Printed Circuit 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](http://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
- 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
- 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