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Notes:

It is the user's responsibility to ensure that this document is the current revision.

All Quality Management System documents are maintained on the Document Control publicread drive.

For approval signatures and detail information on changes see the **DCR** forms located in "**Hist**" folders located on the Document Control drive in the **drawings** folder.

MICROSCAN[®]

Component Qualification Procedure

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Contents

PURPOSE	2
SCOPE	2
REFERENCES	2
PROCEDURE.....	2
SECTION A. COMPONENT QUALIFICATION PROCESS	2
SECTION B. COMPONENT DOCK TO STOCK PROCESS.....	4
SECTION C. COMPONENT DE-CERTIFICATION PROCESS.....	4
SECTION D. QUALITY RECORDS – COMPONENT QUALIFICATION REPORTS	5
TABLE 1 – COMPONENT QUALIFICATION LEVELS	6
FLOWCHART – COMPONENT QUALIFICATION PROCESS.....	7

Purpose

The purpose of this procedure is to provide a common qualification methodology that applies to all purchased custom inventory components for Microscan Systems, Inc. It shall be used in parallel with the Supplier Quality Management Program.

Scope

This procedure applies to all custom inventory components of Microscan Systems, Inc.

References

04-200009	Supplier Quality Management Procedure
04-200010	First Article Inspection Procedure
04-110014	ECN Procedure
04-210004	Process Capability Procedure
04-000024	Corrective/Preventive Action Request Procedure

Procedure

Section A. Component Qualification Process

Responsibility	Action
Quality, Purchasing, Engineering	<p>A-1 New parts shall be released at “Engineering (E)” or “No Inspection Required (NIR)” Status based on the Quality Engineer’s review (See New Part Number Request Procedure). These are the only two qualification levels available for new parts. The proper qualification level is chosen based primarily on the part classification:</p> <p>Custom parts: parts manufactured entirely per Microscan design.</p>

		Spec-controlled parts: parts with some specifications controlled by Microscan (e.g., power supplies, motors)
		Source-controlled parts: standard off-the-shelf components
		Custom and spec-controlled parts are generally released as qualification level E, while source-controlled parts generally do not have inspection requirements, and are released as NIR. In each case, the appropriate status shall be determined by the Quality Engineer.
		Component Qualification Levels: Engineering (E), Pending First Article (PFA), Approved (A), Dock to Stock (DTS), No Inspection Required (NIR) and Obsolete (OBS) (See Table 1 for Detail).
Quality Engineer	A-2	Parts classified as NIR will not have any inspection requirements. This status will be noted in Visual and the Purchased Part Quality Database.
Quality Engineer	A-3	For parts classified as E, Quality to provide information to Engineering on supplier selection, as necessary and available.
Purchasing	A-4	If required by Engineering, engineering parts may be ordered for engineering evaluation and prototyping purposes. Quality will provide inspection support to engineering to aid in the evaluation of the parts.
Quality, Engineering, Purchasing	A-5	Drawing Review with supplier. A review should be conducted with the supplier to assure all requirements can and will be met. Key characteristics should be identified. Changes to drawings shall be requested via the ECN procedure.
Quality Assurance	A-6	Upon completion of a drawing review with the supplier, the component's qualification level shall be promoted to Pending First Article (PFA). Also, parts that have been changed through the ECN process (new dash numbers) enter this process here and are reverted to PFA status regardless of their previous status. The status shall be recorded in the Visual Manufacturing database and the Purchased Part Quality Database (PPQD).
Quality Assurance	A-7	Production First Article Inspection. First article inspection will be performed on the component in accordance with the First Article Inspection Procedure.
Quality, Engineering	A-8	Perform reliability or other testing required by the quality plan. This reliability testing, or at least preliminary testing, may be required prior to approval for certain components such as motors. On other components, testing may be completed after component approval. This decision will be made by the Quality Engineer.
Quality	A-9	Upon first article inspection approval, component is promoted to "Approved (A)" Status. "Approved (A)" Status shall continue to require Receiving Inspection. The Approved status shall be recorded in the Visual Manufacturing database and the Purchased Part Quality Database (PPQD).
Quality	A-10	Data on key characteristics from the first production shipment made may be requested by the Quality Engineer depending upon the criticality of the component and its key characteristics. Alternatively, data collected from engineering shipments may also be used. If such data is obtained, it will be evaluated for process capability and the information used to take any necessary actions on the process or design.
Quality	A-11	Part quality will be monitored through receiving inspection and review of

production defects. Unsatisfactory performance may lead to Supplier Corrective Actions.

Section B. Component Dock to Stock Process.

Responsibility	Action
Quality	<p>B-1 In order to promote a part to "Dock to Stock" status the following requirements must be met.</p> <p>Acceptable process capability ($Cpk > 1.3$) across five consecutive shipments. The shipments must come from distinct production lots from approved suppliers.</p> <p>Or</p> <ol style="list-style-type: none">1. Demonstration by supplier of the existence of a process with adequate process controls that ensure process stability and identify any process instability prior to shipment to Microscan, if such circumstances should arise. This final condition shall be demonstrated through supplier documentation and/or Microscan audits of the supplier.2. No receiving related "negative" incidents over past 12 months from a single supplier.3. No Service or field related "negative" incidents over past six months. <p>Completion of any required reliability tests, as defined in the parent product's Quality Plan.</p>
	<p>B-2 These requirements will be shown to be met in a Component Qualification Report prepared by the Quality Engineer and approved by the Quality Manager.</p>
Quality	<p>B-3 Upon successful completion of the above requirements, the part may be promoted to "Dock to Stock" (DTS) status in the Visual Manufacturing/Purchased Quality Database that will be denoted as DTS/supplier name/CofC example: DTS/Gee Plus/CofC, if a certificate of conformance is required. Receiving will ensure that part has the approved Dock to Stock supplier and CofC is present if applicable. If shipment fails to meet the set criteria than the shipment will be forwarded to QA Receiving for Inspection.</p>

Section C. Component De-Certification Process.

Responsibility	Action
Quality	<p>C-1 It may be necessary to de-certify a part from "Dock to Stock" status based on quality performance issues. Issues that may lead to de-certification include supplier attributable major "negative" incident that impacts Microscan Systems, Inc. Production Lines or Microscan Systems, Inc. Customers.</p>
Quality	<p>C-2 Quality Engineer will demote the part status from "Dock to Stock" to the appropriate status in the Visual Manufacturing Database. Purchasing and Supplier to be informed of change and a SCAR may be requested if</p>

		appropriate.
Quality	C-3	Unless otherwise stated, the part must complete the requirements in Section A and B based on its qualification status in order to be promoted back to "Dock to Stock" status.

Section D. Quality Records – Component Qualification Reports

Responsibility	Action	
Quality	D-1	Collected: Quality Engineer to create and obtain approval.
	D-2	Indexed/Filed: Receiving Inspection History Files by part number.
	D-3	Storage: Receiving inspection area file cabinets. Electronically on shared drive O://Public Read/QA/Component Qualification
	D-4	Access: Open to all Microscan employees, customers, and designated parties.
	D-5	Retention Time: Qualification Reports will be maintained for life of the part.
	D-6	Disposal: Qualification Reports will be disposed or recycled after retention period.

Table 1 – Component Qualification Levels

Qualification Level	Description of Activity	Requirements to Promote
Engineering (E)	Engineering evaluation, components required for engineering evaluation and prototype builds.	Engineering First Article Inspections as required, Document review completed with supplier, Qualification Plan completed.
Pending First Article (PFA)	Qualification for approval is in process. Component requires Production First Article Inspection. Generally used for pilot and pre-production builds.	Approved Production First Article and any required reliability tests
Approved (A)	First article meets drawing requirements. Receiving Inspection is required in accordance with the Quality Plan.	Full proof of ability to maintain stable process at acceptable process capability and completion of all reliability testing
Dock to Stock (DTS)	Inspection at Microscan Systems, Inc. has been eliminated. Parts may be audited for verification purposes.	N/A
No Inspection Required (NIR)	Components that are typically “off the shelf” or “bin stock.” (i.e. standard hardware, passive components, etc...)	No inspection required. Receive directly to stock.
Obsolete (OBS)	Part is no longer used and drawing in document control has been changed to obsolete.	N/A

Flowchart – Component Qualification Process

