

SUPPLIER QUALITY ASSURANCE REQUIREMENTS

QUALITY ASSURANCE

QUALITY REQUIREMENTS SPECIFIED IN THIS DOCUMENT ARE PART OF THE TERMS AND CONDITIONS OF THE PURCHASE ORDER FOR WHICH THEY ARE REFERENCED. FAILURE TO COMPLY MAY RESULT IN WITHHOLDING ACCEPTANCE OF SHIPMENT OR DELAY IN PAYMENT OF INVOICE.

100 Quality Management System

The Supplier shall maintain a Quality Assurance System compliant with the requirements of ISO-9001.

103 CALIBRATION SYSTEM REQUIREMENTS

The Supplier shall maintain a calibration system compliant with the requirements of ISO/IEC 17025.

105 ATEX and IECEx specific requirements.

(Due to length, go to last section for these requirements)

106 ATEX and IECEx specific requirements.

(Due to length, go to last section for these requirements)

107 ATEX and IECEx specific requirements.

(Due to length, go to last section for these requirements)

108 ATEX and IECEx specific requirements.

(Due to length, go to last section for these requirements)

120 Barcode Requirements.

(Due to length, go to last section for these requirements)

205 FIRST ARTICLE INSPECTION

A First Article Inspection submittal and approval is required prior to the first shipment of production product. Samples shall be manufactured from a stable process using the same tooling, processes and methods as planned for during actual production. The first article inspection produced by the Supplier shall include 100% of all dimensions, attributes, and performance tests listed on the drawing.

Note 1: Multi-cavity molds/dies require each cavity to be qualified with an FAI sample. When parts are made from multiple machines, or other machine positions, a first article inspection from each machine and position is required.

A subsequent First Article Inspection re-submission is required whenever:

- 3M Scott design changes have occurred
- Significant supplier process changes have occurred that could affect product form, fit or function,
- Relocation of equipment or production operations within the facilities have occurred that could affect product form, fit or function
- The part is manufactured at a different facility/location,
- There has been more than a twenty four (24) month lapse in production,

- There has been a change in sub-tier suppliers.

First Article Inspection Report: An FAI report containing the actual measurement results for 100% of all characteristics, and evidence of conformance to the drawing notes (e.g., material analysis certifications, test reports and data, etc. as applicable), for the required number of FAI parts is required. The Supplier is required to use the same unit of measure as specified in the technical document package (drawing and specifications) when reporting inspection and test results, unless otherwise specified in the Purchase Order. The original FAI report document package is to be retained by the Supplier.

Packaging and shipping documents shall identify the first article units. Actual production without 3M Scott first-piece inspection approval is solely at the Supplier's risk. Contact 3M Scott Quality to determine the number of first article units required.

207 Supplier Control Plan

The Supplier shall develop a control plan for critical processes which directly affect the quality of the products. A control plan is a documented plan for controlling product and process quality by addressing their key characteristics and engineering requirements.

The control plan should describe the actions that are required at each phase of the process to produce the part.

Product and process characteristic that is determined to require monitoring should be listed in the control plan and monitored to ensure control.

208 Supplier Traceability

The Supplier shall develop and maintain controlled documentation of product traceability during all stages of receipt, production and shipping. Traceability requirement include but are not limited to the following:

- All products and components are traced by lot/batch.
- All serialized product must maintain the traceability during the processing.
- All critical components traced according to 3M Scott's requirement established at the time of qualification.
- All raw materials traced to original material manufacturing lot/batch at a minimum.

The record will be made available to 3M Scott upon request.

301 CHEMICAL/PHYSICAL TEST REPORTS

Upon request, the supplier will provide the original test report containing quantitative data for the material supplied or used in the manufacture of the product.

303 SHELF LIFE CERTIFICATION

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Products shall have no more than 25% of the usable shelf life expired when delivered. Certification shall indicate compliance with above limitations. A signed certification shall be supplied with each shipment and cure and/or manufacture date shall be physically marked on product or packaging.

variable key characteristics, a cpk value of ≥ 1.33 shall be achieved. For all attribute key characteristics, a zero percent defective shall be achieved. Data should be provided to 3M Scott upon request.

313 INSPECTION AND TEST DATA

The supplier is required to maintain records of their Inspection and Test Data for each lot of material shipped. 3M Scott Safety will when necessary, request that data to confirm product acceptability. The data maintained will reflect the identified Critical to Quality Characteristics on the Print, Test Requirements Document (TRD), Engineering Specification, Purchase Order and/or SPQP.

802 NONCONFORMING PRODUCTS

Non-conforming materials and products are to be identified and segregated for review and disposition. Notify 3M Scott Purchasing and Supplier Quality of suspect material at earliest time possible for 3M Scott Quality Action. Shipment of product which fails to conform to 3M Scott drawings and specifications is prohibited without written deviation.

500 SUPPLIER CONTROLLED PRODUCTS/ PROCESSES

The supplier shall Notify 3M Scott Purchasing and Quality prior to incorporating any change or substitutions for product ordered. Changes to tools, fixtures, molds, dies or other process controls, which affect fit, form, or function must have written 3M Scott approval.

900 3M SCOTT/GOVERNMENT-OWNED TOOLING AND FIXTURING

Tooling and fixturing used during the performance of this Purchase Order shall be maintained and stored in such a manner as to prevent damage and deterioration. Periodic tool inspection is to be performed with records of results maintained by the Supplier. Notify 3M Scott Purchasing should tooling require repair, rework or replacement.

701 WORKMANSHIP QUALITY

Finishes of threads, ports, orifices and intersecting holes shall be free of chips, tumbling media, and loose or hanging burrs and be protected for shipment. Areas having a designated surface finish shall be free of irregularities beyond specified acceptance limits.

1200 PACKAGING

All parts and/or assemblies shall be packaged in accordance with all applicable drawings, specifications and special packaging instructions. If specific packaging instructions are not imposed, the best commercial packaging practices must be used to prevent damage.

704 KEY CHARACTERISTICS

Statistical methods such as SPC or other statistical techniques must be used to monitor characteristics classified as key. For all

120 Barcode Requirements.

Barcode and Serial Requirements for Suppliers

General Requirements:

- Labels shall have both a Barcode and Human Readable content.
- All labels shall be of a permanent and indelible marking type.
- The human readable content must be legible.
- The barcode must be scannable by 3M Scott as it is installed on a part.
- Any parts with unreadable barcodes will be returned to Supplier as a nonconforming part.

Serial Number Requirements:

- Unique serialization shall be implemented such that it precludes the possibility of serial number duplication.
- Serial Number format shall contain a unique serial number and a Date of Manufacture code as a minimum.
- Date of Manufacture code shall contain a minimum of Month and Year (Week or Day codes are also acceptable in place of Month).
- Serial numbers must be 30 characters or less.

Barcode Requirements:

- Data Matrix is the preferred format. Note that barcodes smaller than 9.9 mils (.0099") will not be readable.

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- Code 39 may be acceptable, however, it has more limitations. It cannot be used on small or rounded parts. Code 39 smaller than 6.6 mils will not be acceptable.
- The use of Code 39 labels is conditional on first article approval by 3M Scott.

Data Matrix Code 39



Note: Above examples are not to scale

105 ATEX and IECEx REQUIREMENTS

Note: Suppliers which have an ATEX/IECX Quality Assurance Notice (QAN) for the item, component, part or material being supplied are already satisfying the EN 13980 and ISO9001 requirements. For such suppliers, in addition to having a QAN, the Supplier shall satisfy the following noted sections of this document:

- Please note that sections l(FAI) and m(FAIR) must also be satisfied in addition to the Supplier submitting a copy of the QAN relating to the supplied product.
- a) **General Compliance Statement:** - The Supplier is responsible for delivery of product which is compliant with IEC OD/005 (ISO/IEC 80079-34), EN 13980 and ISO9001 requirements. The Supplier shall demonstrate compliance through the life of this Purchase Order, and as required by the cited standards. The following listed sections include clarifications and expansion upon requirements and shall not be considered all inclusive. In the event of a direct conflict existing between any cited standard and the content of this document, the standard takes precedence. Any modifications to the requirements of supplier quality clause #105 must be specified in the governing Purchase Order.

Definitions with stated policy:

- 1) **Explosive Atmosphere Critical or Protective Component (ExCPC):** - An assembly, device, component, or material that has been evaluated or accepted by a certifying body(s) or agency(s) as critical in regard to compliance with explosive atmospheres approval standards. ExCPCs are NOT substitutable and shall be verified and traceable on a 100% basis unless otherwise permitted.
 - 2) **Explosive Atmosphere Critical or Protective Process or Feature:** - A design feature/characteristic or associated process/procedure that has been stipulated by a certifying body or agency as required to ensure/verify continual compliance with explosive atmospheres approval standards.
- b) **Quality Management System:** - The Supplier shall provide for and maintain a Quality Management System (QMS) which is compliant to IEC OD/005 (ISO/IEC 80079-34), EN 13980 and certified ISO9001 and maintain this compliance through the life of the Purchase Order.
- c) **Quality Assurance Plan (QAP):** - The Supplier is to document a QAP that details the method of controls necessary to satisfy the requirements of 3M Scott's Supplier Quality Clause #105. The plan should include other controls, as necessary, to comply with the requirements of the cited standards if not already covered by the Supplier's existing quality system. The QAP shall be documented to an extent which clearly communicates the

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control methods to be utilized. Sub-tier supplier's methods should be included, or referenced by this plan, if essential to the over-all controls necessary by the Supplier to ensure compliance. Emphasis should be placed on detailing the method of identification and traceability that is to be utilized from the receipt of materials to the shipping of product.

The QAP is to be submitted to 3M Scott for review. Also, 3M Scott shall be notified in writing of any subsequent changes to this plan which could affect compliance to requirements. 3M Scott Quality is the primary point of contact for the review of the QAP.

Any modifications to the requirements of Supplier Quality Clause #105 must be documented in the governing Purchase Order in addition to the authorized 3M Scott written consent in order for the change to be considered valid and approved.

- d) **Records:** - The Supplier must maintain all pertinent identification, traceability and conformity records (such as, but not limited to; receiving, testing, inspection records, process documentation revision history, stock issuance "pick lists", process flow "travelers"/work flow routers, nonconformity, shipping and declaration of conformity records) for a minimum of ten (10) years after delivery of the products and services. This includes, but is not limited to, quality records for all significant (safety critical/protective) components assemblies and products, as identified by EN13980 and/or OD 005, contained in the end item assembly. Records shall be maintained in a readily retrievable fashion and stored in an environment and manner which prevents damage, deterioration or loss. Upon request, the Supplier shall make available, at no additional cost to 3M Scott, ALL records necessary to support evidence of compliance.

The Supplier's responsibility is extended to ensuring that all required records generated by Supplier's sub-tier sources are controlled in accordance with this policy, as well. These records shall be maintained accordingly and available for review by 3M Scott, upon request.

- e) **Product Conformance:** - The Supplier is responsible for performing all inspections and tests necessary to substantiate that the product and/or services furnished under this Purchase Order conform to all requirements. Upon request, the Supplier shall make available, at no additional charge cost to buyer, all records necessary to support evidence of such compliance.
- f) **Sampling Inspection Requirement:** - If a sampling plan is used in place of 100% inspection to accept product, the Supplier must use a sampling plan in accordance with ANSI ASQ Z 1.4 with an 1.0 AQL level such that acceptance of each lot is based upon no failures within the sample (Level II, 1.0 AQL, c=0). If one failure is found in the sample the lot shall be rejected. If the Purchase Order or drawing specifies a different sampling plan then it will take precedence.
- g) **Inspection and Testing:** - All measurement and test equipment used by the Supplier to inspect the items to be delivered under this purchase contract shall be calibrated against measurement standards traceable to SI units of measurement (NIST or equivalent). The Supplier shall ensure that products and services provided by sub-tier suppliers comply with all Supplier and 3M Scott requirements. Objective evidence of the performance of tests and inspections shall be maintained by the supplier and provided to 3M Scott upon request and provided with product delivery, if required.
- h) **Calibration Systems Requirements:** - The Supplier shall maintain a calibration system compliant with the requirements of ISO/IEC 17025. Control of monitoring and measuring devices shall conform to IECEx OD/005, EN 13980 and ISO9001.
- i) **Sub-Tier Supplier Compliance:**

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The Supplier shall ensure that their sub-tier suppliers are capable of attaining and maintaining a quality system which is compliant to IEC OD/005 (ISO/IEC 80079-34), EN 13980 and ISO9001 standards for all products, parts and services covered by this Purchase Order. In accordance with these standards, the Supplier's quality program shall contain provisions for surveillance of the sub-tier supplier's quality management system and product quality program activities to ensure compliance.

The Supplier shall ensure that products, services and recordkeeping provided by sub-tier suppliers comply with all requirements as specified by the Supplier, 3M Scott and the required standards. The Supplier has final responsibility to furnish acceptable products, services and records as specified herein.

- j) **Identification:** - Unique serialization of significant (ExCPC) components, sub-assemblies, assemblies and the end product shall be implemented such that it precludes the possibility of serial number duplication. Label formats, and scannable data content, associated with serialization and identification, from components to the end item, are treated as a quality record and shall be maintained accordingly.

j.1) Barcode is required. See 3M Scott Quality Clause #120 for specifics regarding barcode requirements.

- k) **Traceability:** - Material traceability is required with respect to the final product and all of its significant (safety critical/protective) components (ExCPC). Note that Critical/Protective Components are listed in the Components List table of the drawings under the column identified as "ExCPC". The method of traceability shall be established and procedures maintained to control this process. The Supplier's method of control shall take into consideration the sub-tier supplier's controls necessary to ensure compliance. Supplier shall maintain a method of item traceability that ensures tracking of parts back through the supply chain to the manufacturer of all significant components included in assemblies and sub-assemblies being delivered per this Purchase Order. Traceability records shall be able to clearly identify the name and location of all the supply chain intermediaries from the sub-tier supplier's source back to the manufacturer. The manufacturer's information recorded in these records shall include identification as required by the cited standards as specified herein.

Note 1: Scannable barcode (Serial Number and Date Code) shall be in accordance with 3M Scott Quality Clause #120 ("Barcode and Serial Requirements for Suppliers").

- Special Consideration 1: - Printed Circuit Boards (un-populated)
 - k.1) Preferred Shorts and Opens Testing: - Multi-Layer Boards (>2 layers) are to be Net-List tested and individually stamped signifying a passing test. Test stamp is to be applied to the solder side of the board, if practical.
 - k.2) Optional Shorts and Opens Testing: - Each PC Board is to have a 2-sided test utilizing the "Learned Data" technique (Gold Board test) and is to be stamped signifying the test was performed. Golden Board test data is to be learned from the FIRST batch of boards for a specific revision level and this data is to be used for each successive run. Golden Board test data is NOT to be re-learned from each new manufacturing run.
 - k.3) Lot Code / Date Code Marking: - Vendor's ID and Date Code are to be preferably etched into the copper on the solder (bottom) side of the board unless as otherwise directed on the Purchase Order. Supplier to advise 3M Scott of target location for this marking in advance for engineering review and acceptance.
- Special Consideration 2: - Printed Circuit Card assemblies (populated) shall have the following minimum labeling requirements:

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k.4) Assembly Number and Revision

k.5) Serial Number

k.6) Date Code

- l) **First Article Inspection (FAI):** - A First Article Inspection submittal and approval is required prior to the first shipment of production product. Samples shall be manufactured from a stable process using the same tooling, processes and methods as planned for during actual production. The first article inspection produced by the Supplier shall include 100% of all dimensions, attributes, and performance tests listed on the drawing.

Note 2: Multi-cavity molds/dies require each cavity to be qualified with an FAI sample. When parts are made from multiple machines, or other machine positions, a first article inspection from each machine and position is required.

Note 3: 3M Scott approval of the FAI “locks” the Supplier’s, and sub-tier supplier’s, plans/processes from any significant changes that could affect form, fit or function and shall not be modified without written approval by 3M Scott in advance of such a change being made.

Subsequent First Article Inspection resubmission is required whenever:

- l.1) 3M Scott design changes have occurred,
- l.2) significant process changes have occurred that could affect product form, fit or function,
- l.3) relocation of equipment or production operations within the facilities have occurred that could affect product form, fit or function ,
- l.4) the part is manufactured at a different facility/location,
- l.5) there has been more than a twenty four (24) month lapse in production,
- l.6) there has been a change in sub-tier suppliers.

- m) **First Article Inspection Report (FAIR):**

A FAIR copy containing the actual measurement results for 100% of all characteristics, and evidence of conformance to the drawing notes for the required number of FAI parts shall be forwarded to 3M Scott. The Supplier is required to use the same unit of measure as specified in the technical document package (TDP) – for example, drawing and specifications, when reporting inspection and test results, unless otherwise specified in the Purchase Order. An authorized representative of the Supplier’s Quality Department shall review the FAI Report for acceptance. The original FAIR document package is to be retained by the Supplier in accordance with the record retention policy contained herein.

First Article Inspection Report (FAIR) and Test results should be completed and submitted per AS9102 (Note 5).

Note 5: - Alternate methods of FAIR completion and submittal must be agreed upon in writing by 3M Scott Quality prior to submission by the Supplier. Accepted alternate methods shall be clearly documented in the Supplier’s QAP.

- n) **Audit Provision:**

n.1) The Supplier’s Quality Management System, production processes and relevant secondary processes relating to products and services, shall be subject to annual on-site audits by the Buyer’s quality representatives.

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n.2) The Supplier's Quality Management System, production processes and relevant secondary processes relating to products and services, shall be subject to annual on-site audits by the IEC OD/005 (ISO/IEC 80079-34), EN 13980 governing body.

n.3) The Supplier and Supplier's sub-tier suppliers are subject to audits by the IEC OD/005 (ISO/IEC 80079-34), EN 13980 governing body.

Note 6: These site audits are not to result in additional charges to 3M Scott.

- o) **Approved Source of Supply:** - A supplier/distributor specified on the 3M Scott drawing for a significant (safety critical/protective) component or assembly is the only accepted source for this material.
- o.1) **Explosive Atmosphere Critical or Protective Component (ExCPC):** - ExCPCs are NOT substitutable and shall be verified and traceable on a 100% basis unless otherwise permitted.
- p) **Counterfeit Parts Prevention:** All purchased material included in these assemblies being delivered per this Purchase Order must have been procured by the Supplier directly from either the manufacturer of the item(s) or an authorized distributor of the manufacturer of the item(s).
- q) **Declaration Of Conformance (DOC):** The Supplier shall include a legible DOC with each shipment certifying that all items, materials and services supplied meet all 3M Scott requirements including, but not limited to, referenced drawings, specifications and standards. The D.O.C. shall be compliant to 3M Scott requirements and in accordance with EN 13980, ISO/IEC 17050-1, -2. The Supplier shall keep copies of issued DOCs for a minimum period of time (10 years) as required by the Records section of this document.
- r) **Certificate of Analysis:** Each shipment shall be accompanied Certificate of analysis (CoA) of the actual Inspection and Functional Test Report, which reflects the quantitative data on which product acceptance was based. Reports shall be identified to the product by Serial Number or other traceable means.

106 ATEX and IECEx REQUIREMENTS

Note: Suppliers which have an ATEX/IECX Quality Assurance Notice (QAN) for the item, component, part or material being supplied are already satisfying the EN 13980 and ISO9001 requirements. For such suppliers, in addition to having a QAN, the Supplier shall satisfy the following noted sections of this document:

- Please note that sections j(FAI) and k(FAIR) must also be satisfied in addition to the Supplier submitting a copy of the QAN relating to the supplied product.

General Compliance Statement: - An item, component, part or material, as set forth in this quality clause #106, (referred to as "item" henceforth) is associated with an Explosive Atmosphere Critical product and is being produced in accordance with IEC OD/005 (ISO/IEC 80079-34), EN 13980 and ISO9001 requirements. These "items" are 3M Scott source and revision controlled and can be either an ExCPC component itself (e.g., an ExCPC part listed in a Scheduled drawing) or a part which contain(s) explosive atmosphere critical feature(s), process(es) and/or material(s), as identified on the drawings (e.g., an enclosure part containing critical materials // an assembly containing a special process such as a cure time // or a part containing a critical feature or characteristic such as a special dimensional tolerance).

The Supplier is responsible for delivery of items which are compliant with 3M Scott requirements. The Supplier shall demonstrate compliance through the life of this Purchase Order and as required by this document.

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- **Explosive Atmosphere Critical or Protective Component (ExCPC):** If the item has been identified by 3M Scott Requirements as being an explosive atmosphere critical or protective component (ExCPC) then it is NOT substitutable.
- **Explosive Atmosphere Critical or Protective Process or Feature:** If the item has been identified to be or to contain explosive atmosphere critical processes, features, or materials, then changes or substitutions to these features, processes/materials are NOT allowed.

Definitions with stated policy:

1. **Explosive Atmosphere Critical or Protective Component (ExCPC):** - An assembly, device, component, or material that has been evaluated or accepted by a certifying body(s) or agency(s) as critical in regard to compliance with explosive atmospheres approval standards. ExCPCs are NOT substitutable and shall be verified and traceable on a 100% basis unless otherwise permitted.

2. **Explosive Atmosphere Critical or Protective Process or Feature:** - A design feature/characteristic or associated process/procedure that has been stipulated by a certifying body or agency as required to ensure/verify continual compliance with explosive atmospheres approval standards.

a) **Quality Management System:** - The Supplier shall provide for and maintain a Quality Management System (QMS) which is certified to ISO9001 and maintain this compliance through the life of the Purchase Order.

b) **Quality Assurance Plan (QAP):** - The Supplier is to document a QAP that details the method of controls necessary to satisfy the requirements of 3M Scott's Supplier Quality Clause #106. The QAP shall be documented to an extent which clearly communicates the identification, traceability and control methods to be utilized to ensure compliance of identified critical processes and materials.

Sub-tier supplier's methods should be included, or referenced by this plan, if essential to the overall controls necessary by the Supplier to ensure compliance. Emphasis should be placed on detailing the method of identification and traceability that is to be utilized from the receipt of materials to the shipping of product.

The QAP is to be submitted to 3M Scott for review. Also, 3M Scott shall be notified in writing of any subsequent changes to this plan which could affect compliance to requirements. 3M Scott Quality is the primary point of contact for the review of the QAP.

Any modifications to the requirements of Supplier Quality Clause #106 must be documented in the governing Purchase Order in addition to the authorized 3M Scott written consent in order for the change to be considered valid and approved.

c) **Records:** - This quality clause is associated with explosive atmosphere critical components, features, processes and/or materials as identified by the 3M Scott documentation, specifications, and drawings. The Supplier must maintain identification, traceability, and conformity records relating to the critical processes and materials (such as, but not limited to, applicable; receiving, testing, inspection records, process documentation revision history, stock issuance "pick lists", process flow "travelers"/work flow routers, nonconformity, shipping and declaration of conformity records) for a minimum of ten (10) years after delivery of the products and services.

- Specific records shall be maintained for explosive atmosphere critical Material Certifications, Test Certificates, and associated data for purchased materials in order to demonstrate conformance to requirements.

In addition, records shall be maintained to ensure traceability of the materials to the items shipped against the 3M Scott Purchase Order.

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- Specific records shall be maintained for explosive atmosphere critical features and processes to demonstrate conformance to requirements. In addition, records shall be maintained to ensure traceability of the critical features and processes to the items shipped against the 3M Scott Purchase Order.
- Records shall be maintained of unique serialization of (ExCPC) “items”, if serialization is a 3M Scott requirement. Label formats, and scannable data content, associated with serialization and identification, are treated as a quality record and shall be maintained accordingly.

Records shall be maintained in a readily retrievable fashion and stored in an environment and manner which prevents damage, deterioration, or loss. Upon request, the Supplier shall make available, at no additional cost to 3M Scott, ALL records necessary to support evidence of compliance.

The Supplier’s responsibility includes ensuring that all required records generated by Supplier’s sub-tier sources are controlled in accordance with this policy, as well. These records shall be maintained accordingly and available for review by 3M Scott, upon request.

d) **Product Conformance - Inspection and Testing:**

The Supplier is responsible for performing all inspections and tests necessary to substantiate that the items, materials, product and/or services furnished under this Purchase Order conform to all requirements. Upon request, the Supplier shall make available, at no additional cost to buyer, all records necessary to support evidence of such compliance.

Objective evidence of Material Certifications, Testing and Data, as required by 3M Scott requirements, shall be maintained by the Supplier and provided to 3M Scott upon request and provided with product delivery, as required.

Objective evidence of the performance of inspections and testing shall be maintained by the Supplier and provided to 3M Scott upon request and provided with product delivery, if required.

e) **Calibration Systems Requirements:** - The Supplier shall maintain a calibration system compliant with the requirements of ISO/IEC 17025. Control of monitoring and measuring devices shall conform to IECEx OD/005, EN 13980 and ISO9001.

All measurement and test equipment used by the Supplier to inspect and test the items to be delivered under this purchase contract shall be calibrated against measurement standards traceable to SI units of measurement (NIST or equivalent). The Supplier shall ensure that products and services provided by sub-tier suppliers comply with all Supplier and 3M Scott requirements.

f) **Sampling Inspection Requirement:** - If a sampling plan is used in place of 100% inspection to accept product, the Supplier must use a sampling plan in accordance with ANSI ASQ Z 1.4 with an 1.0 AQL level such that acceptance of each lot is based upon no failures within the sample (Level II, 1.0 AQL, c=0). If one failure is found in the sample, the lot shall be rejected. If the Purchase Order or drawing specifies a different sampling plan then it will take precedence.

g) **Sub-Tier Supplier Compliance:** The Supplier shall ensure that their sub-tier suppliers, who are supplying Explosive Atmosphere Critical or Protective Components (ExCPC), Protective Processes or Features, as identified on the drawing, are capable of attaining and maintaining a quality system which is compliant to IEC OD/005 (ISO/IEC 80079-34), EN 13980 and ISO9001 standards for all products, parts and services covered by this Purchase Order. In accordance with these standards, the Supplier’s quality program shall contain provisions for surveillance of the sub-tier supplier’s quality management system and product quality program activities to ensure compliance.

The Supplier shall ensure that products, services and recordkeeping provided by sub-tier suppliers comply with all requirements as specified by the Supplier, 3M Scott and the required standards. The Supplier has final responsibility to furnish acceptable products, services, and records as specified by this document.

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h) **Identification:** Unique serialization of significant (ExCPC) components, if required by the drawing, shall be implemented such that it precludes the possibility of serial number duplication. Label formats, and scannable data content associated with serialization and identification shall be controlled and maintained accordingly.

- See 3M Scott Quality Clause #120 for specifics regarding barcode requirements, if applicable.

i) **Traceability:** - Traceability of an ExCPC component itself or for explosive atmosphere critical feature(s), process(es) and/or material(s) is required. The traceability method utilized must tactically function in a “forward looking” (purchased material to shipped product) and in a “backward looking” manner (from a shipped product back to purchased material). The method of traceability shall be established and procedures maintained to control this process.

The Supplier’s method of control shall take into consideration, if applicable, the sub-tier supplier’s controls necessary to ensure compliance. Supplier shall maintain a method of “item” traceability that ensures tracking of parts back through the supply chain to the origin of application or manufacture of all explosive atmosphere critical feature(s), process(es) and/or material(s). Traceability records shall be able to clearly identify the name and location of all the supply chain intermediaries from the sub-tier supplier’s source back to the manufacturer.

i.1) Explosive atmosphere critical materials shall be traceable to the manufactured batch / lot at a minimum and include traceability to all required material certifications, testing and data.

- The ExCPC component traceability requirements encompass the ability to link.
- Explosive atmosphere critical materials shall be traceable to the manufactured batch / lot at a minimum and include traceability to all required material certifications, testing and data.

j) **First Article Inspection (FAI):** - A First Article Inspection submittal and approval is required prior to the first shipment of production product. Samples shall be manufactured from a stable process using the same tooling, processes and methods as planned for during actual production. The first article inspection produced by the Supplier shall include 100% of all dimensions, attributes, and performance tests listed on the drawing.

Note 1: Multi-cavity molds/dies require each cavity to be qualified with an FAI sample. When parts are made from multiple machines, or other machine positions, a first article inspection from each machine and position is required.

Note 2: 3M Scott approval of the FAI “locks” the Supplier, and sub-tier suppliers’, plans/processes from any significant changes that could affect form, fit, or function and shall not be modified without written approval by 3M Scott in advance of such a change being made.

Subsequent First Article Inspection resubmission is required whenever:

- j.1) 3M Scott design changes have occurred (see Note 3),
- j.2) significant process changes have occurred that could affect product form, fit, or function (see Note 3),
- j.3) relocation of equipment or production operations within the facilities have occurred that could affect product form, fit, or function (see Note 3),
- j.4) the part is manufactured at a different facility/location,
- j.5) there has been more than a twenty-four (24) month lapse in production,
- j.6) there has been a change in sub-tier suppliers (see Note 3).

Note 3: Delta FAI: The FAI resubmission requirements may be satisfied by addressing differences between current configuration and prior approved configurations.

SUPPLIER QUALITY ASSURANCE REQUIREMENTS

QUALITY ASSURANCE

QUALITY REQUIREMENTS SPECIFIED IN THIS DOCUMENT ARE PART OF THE TERMS AND CONDITIONS OF THE PURCHASE ORDER FOR WHICH THEY ARE REFERENCED. FAILURE TO COMPLY MAY RESULT IN WITHHOLDING ACCEPTANCE OF SHIPMENT OR DELAY IN PAYMENT OF INVOICE.

k) **First Article Inspection Report (FAIR):**

A FAIR copy containing the actual measurement results for 100% of all characteristics, and evidence of conformance to the drawing notes for the required number of FAI parts shall be forwarded to 3M Scott. The Supplier is required to use the same unit of measure as specified in the technical document package (TDP) – for example, drawing and specifications, when reporting inspection and test results, unless otherwise specified in the Purchase Order. An authorized representative of the Supplier's Quality Department shall review the FAI Report for acceptance. The original FAIR document package is to be retained by the Supplier in accordance with the record retention policy contained herein.

First Article Inspection Report (FAIR) and Test results should be completed and submitted per AS9102 (Note 4).

Note 4: Alternate methods of FAIR completion and submittal must be agreed upon in writing by 3M Scott Quality prior to submission by the Supplier. Accepted alternate methods shall be clearly documented in the Supplier's QAP.

l) **Locked Processes:** 3M Scott approval of the Supplier's quality assurance plan (QAP), or first article inspection report, "locks" the Supplier's, and sub-tier suppliers', plans/processes from any significant changes that could affect form, fit, or function and shall not be modified without written approval by 3M Scott in advance of such a change being made.

m) **Audit Provision:**

m.1) The Supplier's Quality Management System, production processes and relevant secondary processes relating to products and services, shall be subject to annual onsite audits by the Buyer's quality representatives.

m.2) The Supplier's Quality Management System, production processes and relevant secondary processes relating to products and services, shall be subject to annual onsite audits by the IEC OD/005 (ISO/IEC 80079-34), EN 13980 governing body.

m.3) The Supplier and the Supplier's sub-tier suppliers are subject to audits by the IEC OD/005 (ISO/IEC 80079-34), EN 13980 governing body.

Note 5: These site audits are not to result in additional charges to 3M Scott.

n) **Approved Source of Supply:** - A Supplier/distributor specified on the 3M Scott drawing for a significant (safety critical/protective) component, process or assembly is the only accepted source for this item.

n.1) **Explosive Atmosphere Critical or Protective Component and Materials (ExCPC):** - ExCPCs are NOT substitutable and shall be verified and traceable on a 100% basis.

o) **Counterfeit Parts Prevention:** All purchased material included in these assemblies being delivered per this Purchase Order must have been procured by the Supplier directly from either the manufacturer of the item(s) or an authorized distributor of the manufacturer of the item(s).

p) **Declaration Of Conformance (DOC):** - The Supplier shall include a legible DOC with each shipment certifying that all items, materials and services supplied meet all 3M Scott requirements including, but not limited to, referenced drawings, specifications and standards. The DOC shall be compliant with 3M Scott requirements and in accordance with EN 13980, ISO/IEC 17050-1, -2. The Supplier shall keep copies of issued DOCs for a minimum period of time (10 years) as required by the Records section of this document.

p.1) Material certifications, material test reports and data associated with explosive atmosphere critical materials shall be included with each DOC.

SUPPLIER QUALITY ASSURANCE REQUIREMENTS

QUALITY ASSURANCE

QUALITY REQUIREMENTS SPECIFIED IN THIS DOCUMENT ARE PART OF THE TERMS AND CONDITIONS OF THE PURCHASE ORDER FOR WHICH THEY ARE REFERENCED. FAILURE TO COMPLY MAY RESULT IN WITHHOLDING ACCEPTANCE OF SHIPMENT OR DELAY IN PAYMENT OF INVOICE.

p.2) Inspection and testing records associated with explosive atmosphere critical feature(s), process(es) and/or material(s) shall be included with each DOC.

107 ATEX and IECEx REQUIREMENTS

- a) **General Compliance Statement:** - This item, part, or material is associated with an Explosive Atmosphere Critical product and is being produced in accordance with IEC OD/005 (ISO/IEC 80079-34), EN 13980 and ISO9001 requirements. The item, part, or material being purchased is considered to be a source control/revision controlled item which is managed and controlled by 3M Scott. Substitutions or changes to the requirements are NOT allowed without written consent from 3M Scott. Any 3M Scott approved changes must be noted in the 3M Scott Purchase Order for their being considered approved and accepted.
- b) **Quality Management System:** - The Supplier shall provide for and maintain a Quality Management System (QMS) which is compliant with ISO9001 and maintain this certification through the life of the Purchase Order. A copy of the Supplier's current ISO9001 certificate is to be provided to 3M Scott on a yearly basis to demonstrate continued certification. 3M Scott will advise the Supplier when copies of the ISO9001 certificate are needed.
- c) **Records:** - The Supplier must maintain all pertinent identification, traceability, and conformity records in accordance with ISO9001 requirements. Records shall be maintained in a readily retrievable fashion and stored in an environment and manner which prevents damage, deterioration, or loss. Upon request, the Supplier shall make available, at no additional cost to 3M Scott, ALL records necessary to support evidence of compliance.
- d) **Product Conformance:** - The Supplier is responsible for performing all inspections and tests necessary to substantiate that the product and/or services furnished under this Purchase Order conform to all requirements. Upon request, the Supplier shall make available, at no additional charge cost to buyer, all records necessary to support evidence of such compliance.
- e) **First Article Inspection (FAI):** - A First Article Inspection submittal and approval is required prior to the first shipment of production product. Samples shall be manufactured from a stable process using the same tooling, processes, and methods as planned for during actual production. The first article inspection produced by the Supplier shall include 100% of all dimensions, attributes, and performance tests listed on the drawing.

Note 1: Multi-cavity molds/dies require each cavity to be qualified with an FAI sample. When parts are made from multiple machines, or other machine positions, a first article inspection from each machine and position is required.

Note 2: 3M Scott approval of the FAI "locks" the Supplier's, and sub-tier supplier's, plans/processes from any significant changes that could affect form, fit, or function and shall not be modified without written approval by 3M Scott in advance of such a change being made.

Subsequent First Article Inspection resubmission is required whenever:

- e.1) 3M Scott design changes have occurred (see Note 3),
- e.2) significant process changes have occurred that could affect product form, fit, or function (see Note 3),
- e.3) relocation of equipment or production operations within the facilities have occurred that could affect product form, fit, or function (see Note 3),
- e.4) the part is manufactured at a different facility/location,
- e.5) there has been more than a twenty four (24) month lapse in production,

SUPPLIER QUALITY ASSURANCE REQUIREMENTS

QUALITY ASSURANCE

QUALITY REQUIREMENTS SPECIFIED IN THIS DOCUMENT ARE PART OF THE TERMS AND CONDITIONS OF THE PURCHASE ORDER FOR WHICH THEY ARE REFERENCED. FAILURE TO COMPLY MAY RESULT IN WITHHOLDING ACCEPTANCE OF SHIPMENT OR DELAY IN PAYMENT OF INVOICE.

e.6) there has been a change in sub-tier suppliers (see Note 3).

Note 3: Delta FAI: The FAI resubmission requirements may be satisfied by addressing differences between current configuration and prior approved configurations.

f) **First Article Inspection Report (FAIR):**

A FAIR copy containing the actual measurement results for 100% of all characteristics, and evidence of conformance to the drawing notes for the required number of FAI parts shall be forwarded to 3M Scott. The Supplier is required to use the same unit of measure as specified in the technical document package (TDP) – for example, drawing and specifications, when reporting inspection and test results, unless otherwise specified in the Purchase Order. An authorized representative of the Supplier's Quality Department shall review the FAI Report for acceptance. The original FAIR document package is to be retained by the Supplier and made available upon 3M Scott request.

g) **Counterfeit Parts Prevention:** - All purchased parts and materials delivered per this Purchase Order must have been procured by the Supplier directly from either the manufacturer of the item(s) or an authorized distributor of the manufacturer of the item(s).

h) **Certificate Of Conformance (COC):** - The Supplier shall include a legible COC with each shipment to indicate that the supplied items, materials, and product are in accordance with all 3M Scott Purchase Order requirements.

108 ATEX and IECEx REQUIREMENTS

a) **General Compliance Statement:** - This item, part, or material is associated with an Explosive Atmosphere Critical product and is being produced in accordance with IEC OD/005 (ISO/IEC 80079-34), EN 13980 and ISO9001 requirements. The item, part, or material being purchased is considered to be an "Off The Shelf" item which is managed and controlled by the manufacturer of the product. 3M Scott does not maintain source or revision controls for this part. The following sections detail the 3M Scott requirements for this item.

b) **Quality Management System:** - The Supplier shall provide for and maintain a Quality Management System (QMS) which is compliant with ISO9001, and maintain this certification throughout the life of the Purchase Order. A copy of the Supplier's current ISO9001 certificate is to be provided to 3M Scott on a yearly basis to demonstrate continued certification. 3M Scott will advise the Supplier when copies of the ISO9001 certificate are needed.

c) **Counterfeit Parts Prevention:** - All purchased parts and materials delivered per this Purchase Order must have been procured by the Supplier directly from either the manufacturer of the item(s) or an authorized distributor of the manufacturer of the item(s).

d) **Certificate Of Conformance (COC):** - The Supplier shall include a legible COC with each shipment to indicate that the supplied items, materials, and product are in accordance with the 3M Scott Purchase Order requirements.