

Fluke Supplier Quality Manual



Dear Fluke Supplier,

The Fluke Supplier Quality Manual was written for you to better understand Fluke and Fluke's engagement with you, our valued Supplier. I would especially encourage you to review our mission and quality policy along with the links to Fortive's Values, Supplier Code of Conduct, and expectations for Integrity and Compliance. This will go a long way in understanding Fluke, how we conduct business, and how we expect our Suppliers to comply.

There are two sections to this Quality Manual. The first focuses on quality system expectations of Suppliers, and the second on purchasing processes and requirements. Please take the time to read, and should you have any questions, please contact your Fluke Commodity Manager for clarification.

Thank you for your support.

Sincerely,

Jason Shaffer

Jason Shaffer
Director of Global Quality & EHS
4 February 2024

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FLUKE Corporation is a subsidiary of FORTIVE Corporation (FTV)
FLUKE Corporation or its subsidiaries (Fluke)

[FLUKE CORPORATE QUALITY POLICY](#)

[FORTIVE CORE VALUES](#)

[FORTIVE SUPPLIER CODE OF CONDUCT](#)

[FORTIVE INTEGRITY AND COMPLIANCE](#)

[FORTIVE BUSINESS SYSTEMS](#)

1. INTRODUCTION TO THE FLUKE SUPPLIER QUALITY MANUAL

The [Fortive Core Values](#) reflect who we are and the [Fortive Business System \(FBS\)](#) is fundamental to how we do what we do. FBS is more than a management system or business model - it is part of Fluke personnel's mentality. Through FBS, Fluke achieves world-class excellence in customer satisfaction, beginning with the voice of the customer, continuously improving quality, delivery, cost, and innovation.

FBS is at the core of our quality system. We focus on defect prevention, contrary to defect detection. Suppliers must employ a valid methodology and error-proofing of their manufacturing processes to achieve zero defects. To achieve zero defects, it is recommended that the Supplier has procedures in place using six sigma and lean manufacturing methodologies.

1.1 PURPOSE, SCOPE, AND ACCESSIBILITY

The Fluke Supplier Quality Manual details Fluke's values, expectations, requirements, and how we work with our Suppliers in a long-term business relationship. It is essential to follow these requirements to ensure materials and components are not delayed or rejected at receiving.

This Quality Manual applies to all Suppliers of raw material, components, goods, and services to any Fluke facility except when the specific requirements may vary due to their customer flow downs (e.g., Janos Technology). Any exceptions for specific customer requirements should be documented in Local Process Documents, contracts, purchase orders, or specifications.

This document does not contain confidential information and may be shared with personnel outside the Fluke and Fortive.

2. QUALITY SYSTEM EXPECTATIONS AND REQUIREMENTS

A Supplier's ability to develop and maintain an acceptable quality system is essential in qualifying and continuing as a Fluke Supplier.

2.1 SUPPLIER RESPONSIBILITIES

Suppliers are responsible for maintaining a quality system that ensures each product complies with the requirements included in the engineering drawing, Purchase Orders (PO), contracts, and outlined in this Quality Manual.

If the Supplier accepts a PO from Fluke, the Supplier agrees with the terms and conditions and this Quality Manual.

Suppliers are responsible for all of their outsourced processes and subcontractors' quality performance. Suppliers shall ensure that externally provided processes,

products and services are controlled and conform to Fluke requirements. When a subcontractor generates a nonconformance, the Supplier is to review the subcontractor process control system to ensure their performance re-aligns to Flukes expectations.

2.1.1 Confidentiality and Intellectual Property

Suppliers shall maintain the confidentiality of our organization's proprietary information and intellectual property. Any information shared by our organization shall be used solely for the purpose of fulfilling the agreed-upon requirements.

2.1.2 Compliance with Applicable Laws and Regulations

Suppliers shall comply with all applicable laws, regulations, and industry standards related to their products or services. Suppliers shall promptly inform our organization of any changes in legal or regulatory requirements that may impact their ability to meet our needs.

2.1.3 Records and Documentation

Suppliers shall maintain records and documentation related to their products or services in accordance with applicable standards and regulatory requirements. Records shall be retained for the specified period and made available for review upon request.

2.2 FORTIVE/FLUKE PART QUALIFICATION PROCESS

The Fortive/Fluke Part Qualification Process (FPQP) is used to develop or qualify parts for Fluke. The FPQP process is also used when a Supplier moves a manufacturing location to another site, there is a significant change to the design specification, or when requalification is required due to chronic quality problems. Training for the FPQP process can be found using the following link: [FPQP Supplier Training](#).

2.3 FLUKE ENGINEERING DRAWINGS

When conflicts exist between engineering drawings, the PO, and/or this Supplier Quality Manual, engineering drawings shall supersede any other document and will be the primary source of quality requirements; Fluke PO will be secondary, followed by this Quality Manual.

Suppliers are responsible for understanding all engineering drawings and specification requirements. If any questionable areas appear to exist, the Supplier must contact Fluke engineering for clarification. Drawing clarifications must be resolved before the manufacturing of production parts. Only deviations provided

and authorized by Fluke Engineering may supersede engineering drawings and specifications.

Suppliers may establish internal critical characteristics and performance testing criteria aligned with Fluke's critical characteristics and performance criteria indicated in the Fluke drawing and implement appropriate controls for each.

Suppliers are responsible for communicating the Fluke engineering drawings' requirements, Fluke PO, [Fluke Appearance Standard Policy](#), and this document to their subcontractors.

2.3.1 Workmanship Standards

Workmanship standards are defined by the following, except where explicitly called out in product/service specific controlling documents (such as work instructions, procedures, or design disclosure drawings):

1. IPC-A-610 Acceptability of Electronic Assemblies and IPC-7711/7721 Rework, Modification and Repair of Electronic Assemblies. These external documents cover many types of technologies and workmanship criteria for new and reworked electronic assemblies.

In order to limit the risks associated with excessive rework, it is recommended not to exceed three of each of the following per board:

- a. Jumper wires installed to repair PCA or PCB defects
- b. Repairs to lifted or removed pads
- c. Repairs to lifted Traces

Use of boards exceeding three of any of these repair types requires the approval of Fluke Engineering.

2. [Fluke Appearance Standard Policy](#)

2.4 ORIGINAL EQUIPMENT MANUFACTURER

Suppliers who are Original Equipment Manufacturers (OEMs) that control the product's design shall maintain technical documentation, such as DFMEA, PFMEA, Process Flow Diagram, and Control Plan.

2.5 SUPPLIER PRODUCT QUALITY

Suppliers are responsible for their products' quality and do not rely on Fluke to determine their material or service quality level. The use of a recognized sampling technique is not intended to imply that defective material at any level is acceptable. Any defect found in a Fluke facility requires prompt investigation of the

product failure mode, understanding root cause, and taking appropriate corrective action.

Suppliers are responsible for notifying Fluke of any proposed design or process changes, or any other significant changes (such as change of manufacturing location, component End of Life, outsourced product, or process changes, etc.). Suppliers must obtain Fluke's written approval of any proposed changes and Fluke's acknowledgement of any other significant changes.

Supplier shall obtain Fluke's approval when any of the following are changed or updated: critical equipment, fixtures, tooling, or key manufacturing parameters.

Suppliers are responsible for implementing the [Fluke Appearance Standard Policy](#) in the final inspection. Suppliers are also responsible for implementing the Fluke Serialization and Part Marking Policy, as applicable and communicated by Fluke, in the final inspection. If there is a concern in using these standards, Suppliers must communicate it to the appropriate Commodity Manager.

2.6 CALIBRATION AND TESTING

Suppliers providing calibration or testing services shall comply with ISO/IEC 17025 requirements, if applicable. Calibration and testing equipment shall be properly maintained, calibrated, and traceable to national or international standards. Suppliers shall provide calibration certificates or test reports with accurate and reliable results.

2.7 NONCONFORMING MATERIAL

Suppliers are responsible to rework or replace nonconforming material to Fluke specification in time to meet Fluke delivery requirements. In some cases, material urgently required to complete customer shipments may be reworked by Fluke at the Supplier's expense.

Where nonconforming material need to be returned to the Supplier, an RMA or equivalent authorization is to be provided within 48 hours.

2.8 SUPPLIER CORRECTIVE ACTION REQUEST (SCAR)

A SCAR may be initiated when product is delivered late because of reasons attributable to the Supplier, as part of the Material Review Board (MRB) disposition, or upon discovering any Supplier caused issues during the products' lifecycle. SCARs may also be initiated on first article failures, poor cumulative Supplier performance over time, unacceptable scorecard, and/or other performance deficiencies.

It is recommended that the Supplier should complete and submit the Root Cause analysis within 30 days and the Corrective Action Implementation within 60 days of receiving a SCAR.

2.9 FLUKE PROPERTY

Fluke-owned tooling, instruments, fixtures, and any other piece of equipment shall be permanently identified as Fluke property and be stored and maintained as per the terms and conditions outlined in the PO.

2.10 PRODUCT COMPLIANCE REGULATIONS

Suppliers are responsible for complying with all specified safety, regulatory and environmental compliance requirements detailed for Fluke products and components. The Supplier is also expected to be a collaborative partner in resolving compliance-related questions with these regulations.

Purchased products or components with safety and/or compliance requirements are flagged as “Critical to Fluke Product Compliance and Safety” in the PO.

Unless requested or agreed otherwise, a Certificate of Conformity (CoC) must be supplied to Fluke with each lot of components or product critical to Fluke product compliance and safety. The CoC data must include a statement of conformity, including reference to any relevant quality management system standards, for example:

Declaration of Conformity: The items detailed herein conform to the requirements of the purchase order number as detailed above unless otherwise stated and have been manufactured in accordance with appropriate Fluke engineering requirements and industrial regulations indicated in the PO.

2.10.1 EXPLOSIVE ATMOSPHERE (ATEX) DIRECTIVE

The Supplier selection process for components used in a Fluke Ex instrument must meet the specific requirements listed in the [ATEX Requirements](#).

If the purchased product or component is flagged “Critical to Fluke Product Compliance and Safety” and “Fluke product certified for use in Explosive Atmospheres” in the PO. The Supplier must meet Fluke specification and PO instructions as indicated.

Unless requested or agreed otherwise, a Certificate of Conformity (CoC) should be supplied to Fluke using the “[ATEX Supplier CoC Template](#)” with each batch of components for all Fluke products certified for use in explosive atmospheres.

In cases where the Supplier uses their own CoC template, it must include the following information:

- Unique Identifier
- Supplier name
- Purchase order number
- Purchase order line item number
- Fluke part number
- Part description
- Fluke drawing revision
- Quantity
- Process specification number if applicable
- CoC of any treatments or processes from subcontractors
- Manufacturer's name
- If appropriate, traceability data (such as melt or heat number, batch, serial number, lot/date code, or cure date)
- Supplier's authorized representative name, signature, title, and contact address
- Place (if different than contact address) and date of issue

The CoC should also include an unambiguous statement detailing the Supplier's conformity, inspection, test, and compliance with the purchase order requirement.

The Supplier shall retain CoC and test data for a minimum period of 10 years. Upon request, the Supplier shall provide evidence of retention.

No changes can be made without Fluke's written approval; verbal approvals are not acceptable. As needed, Fluke may perform an annual ATEX audit to ISO/IEC 80079-34 at the Supplier facility.

2.10.2 ENVIRONMENTAL REGULATORY COMPLIANCE

All components on bills of materials and other parts (grease, epoxy, wiring, solder) used in the manufacturing process to make finished products must be compliant with EU RoHS 2 (Directive 2011/65/EU). Subsequently, EU RoHS 3 (Directive 2011/65/EU as amended by 2015/863/EU), Compliance validation documents, including REACH, Prop 65, China RoHS, and EU RoHS declarations/ certificates of conformity must be provided for each component, except if the part has been designated as out-of-scope of EU RoHS, in which case RoHS data may not be required.

2.11 MEDICAL DEVICES

The Supplier selection process for components used in a Medical Device must meet the specific requirements listed in the [Medical Device Supplier Requirements](#).

Suppliers manufacturing OSP medical devices are responsible for retaining quality records equivalent to the lifetime of the device. Records are available for review by regulatory authorities, quality system auditors, and Fluke personnel when specified as part of their contract.

2.12 SUPPLIER PACKAGING REQUIREMENT

The [Supplier Packaging Quality Manual](#) provides a structured guide for packaging specification. The Supplier adherence to the packaging specification will ensure the timeliness and accuracy of invoice payments.

Best practice guidelines for product packaging labeling may be found in PROCURExx Product Packaging Labeling Requirements.

2.13 ISO CERTIFICATION

Suppliers who maintain a continuing business relationship with Fluke must demonstrate that they have a quality system that meets or exceeds Fluke's requirements, for example, ISO 9001. Suppliers with ISO certification must provide a copy of the ISO certificate. Current Suppliers who do not meet these criteria are expected to be working toward a viable quality system complying with a standard, such as ISO 9001.

Suppliers are responsible for providing quality performance records upon request.

Suppliers shall participate in the Fortive Supplier Assessment process using the "[FTV Supplier Evaluation Tool](#)," which contains questions that allow Fluke or the Supplier to evaluate the extent to which a given quality system addresses each of these elements. This applies to all Fluke Suppliers except where, due to their customer flow downs, the specific requirements may vary (e.g., Suppliers for Janos Technology). Any exceptions for specific requirements should be documented in Fluke Local Process Documents.

2.14 APPROVED SUPPLIER LIST (ASL)

After a thorough review and evaluation of their overall business health, technology, and ability to manufacture products that meet Fluke's requirements, Suppliers are selected. Fluke reserves the right to perform audits of the Supplier's quality system and manufacturing facilities. Following a fair assessment of the Supplier's complete evaluation, the Supplier is included in the Approved Supplier List (ASL).

Ongoing Supplier performance is measured by monitoring quality, delivery, and cost performance. Any Supplier failing to meet the Fluke Performance requirements may be subject to removal from the ASL.

Supplier status is noted on the ASL as either:

- a. **Preferred:** a managed group of Suppliers who align with Fluke's strategic vision and performance expectations, as outlined in the Preferred Supplier Program
- b. **Qualified:** Supplier can be anyone that meets our business need and is not in violation of governing laws of the land
- c. **Disqualified:** Suppliers who have been assessed in the past but have been removed from the ASL or who have not met the minimum Fluke's requirements

2.15 BEGINNING THE SUPPLIER APPROVAL PROCESS

To initiate the Fluke Supplier Approval Process, Suppliers must first provide a signed copy of the [FTV Supplier Code of Conduct](#) and any applicable compliance documents (e.g., RoHS, REACH, Prop 65, TSCA, PFAS, and PoPS). Suppliers should also provide a completed [FTV Supplier Evaluation Tool](#) and any ISO certifications and/or quality manuals as part of this process.

NOTE 1: All Fluke Suppliers are required to comply with the Fluke Supplier Quality Manual. Supplier resource limitations do not automatically prohibit participation in the Fluke Supplier Approval Process. Please contact Fluke Supplier Quality for assistance if there are any questions or concerns.

NOTE 2: For the ATEx Supplier Evaluation Process, please contact Fluke Supplier Quality for the correct ATEx Supplier Evaluation Tool or any other assistance.

2.16 QUALITY SYSTEM AUDIT

After reviewing the Supplier's quality manual and the [FTV Supplier Evaluation Tool](#), or when supply chain risk, critical technology, chronic quality issues, single-source supply, or other risks are identified, Fluke may request that an on-site quality system audit be conducted.

The audit conducted at the Supplier's manufacturing location will determine conformance to the Fluke quality requirements.

2.17 PREFERRED SUPPLIER PROGRAM

Preferred Suppliers are fundamental to Fluke's success. The preferred Supplier program's objective is to develop our supply base to consistently provide parts that meet the quality, delivery, cost, and service objectives to maintain Fluke as a world-class manufacturer.

The preferred supply base is a managed group of Suppliers who align with Fluke's strategic vision and performance expectations. Fluke will focus on growth and consolidation efforts with these Suppliers. Selected preferred Suppliers will have the opportunity to learn appropriate FBS tools and Kaizen to improve quality and processes. The preferred Supplier program supports all commodities in Fluke.

Fluke awards preferred Supplier status to Suppliers that meet the following criteria:

PREFERRED SUPPLIER CRITERIA	Fortive Tenure	Strategic Alignment	Supplier Audits	Business Continuity	Supplier Quality	Payment Terms	QDCI Performance
Current Supplier With Fortive Opco(s) For 1+ Year	✓						
Commodity Team Approval For 'Preferred' Status		✓					
Designated As "Grow" Supplier By Opco(s)		✓					
Fortive Supplier Audit Score Of >70% For Each Section			✓		✓		✓
Formal Approved Business Continuity Plan (< 3 Years In Age)				✓			
Payment Terms Of Net 90 Or Equivalent						✓	✓
Meets All QDCI & Regulatory Requirements For FTV Opco(s) Served					✓		✓
Warranty Parts & Service For 1+ Year(s)							✓
Continuous Cost Improvement Commitment (5%+ Expectation)							✓
Master Supply Agreement		✓	✓	✓	✓	✓	✓

2.18 QUALITY SYSTEMS ASSESSMENT

The audit checklist and scoring guidelines included in the [FTV Supplier Evaluation Tool](#) reflect the elements expected of a sufficient quality system and will be used in Fluke's evaluation of a Supplier's quality system. The audit summary should not be confused with a Supplier rating system or scorecard, which might include such performance factors as quality of received material, on-time delivery, etc.

Supplier quality systems should aim to prevent defects through product qualification, planning and process control techniques. This approach leads to increased productivity and continuous improvement in quality.

The minimum target score is 70% in each section of the [FTV Supplier Evaluation Tool](#) document for approval. If a Supplier's score is below 70% in the final section, they must have a corrective action plan to improve performance.

The corrective action plan will be tracked by Fluke Supplier Quality and reassessed when corrective actions have been implemented.

2.19 DISQUALIFICATION

Any Supplier failing to meet the quality or performance requirements is subject to removal from Fluke's ASL.

3. PURCHASING PROCESS AND REQUIREMENTS

This section defines the Fluke procurement process, including requests for quotation, initial Supplier approval, contracts and PO, shipping and transportation, communications, expectations concerning cost savings, proprietary information, and Supplier performance rating.

3.1 REQUEST FOR QUOTATION (RFQ) ACTIVITIES

The Fluke Procurement Team and New-Product Introduction (NPI) Buyers will submit RFQs to potential Suppliers.

The RFQ will include the following:

- [FTV Supplier Code of Conduct](#)
- [Link to download the Fluke Supplier Quality Manual](#)
- [Link to download the Packaging Quality Manual for Suppliers](#)
- [Link to download the Fluke Appearance Standard](#)
- [Link to access FPQP Supplier Training](#)
- [Supplier Acknowledgment of Understanding Form](#)
- Work Package
- Terms and Conditions
- Bid Due Date
- Method of shipment and FOB point
- Terms of payment
- Engineering Drawing
- Request for Country of Origin, RoHS, or any other applicable regulatory requirements
- If the required part is used in an Ex instrument, Suppliers must comply with the ISO/IEC 80079-35874 ATEX Standard
 - [ATEX Supplier Acknowledgement of Understanding Form](#)
 - For the ATEX CoC template, use this link: [ATEX CoC Template](#)
- If the required part is used in a Medical Device, Suppliers must comply with the ISO 13485 Medical Device Standard
- All other pertinent information to ensure the accuracy of the RFQ process

The Supplier quotation should be returned to the requestor and include the following:

- All requested quote information
- Supplier acceptance of Fluke Terms and Conditions
- Suppliers shall use Fluke endorsed carriers when Fluke incurs transportation costs. A list of approved carriers is available from the buyer and is updated annually
- Country of Origin, RoHS certification, or any other applicable regulatory requirements
- Supplier Acknowledgment of Understanding Form or ATEX Supplier Acknowledgement of Understanding Form
- Copy of ISO 13485 or ISO 9001 certifications as a minimum requirement if the material will be used in a medical device

3.2 PROPRIETARY INFORMATION

Fluke will initiate a Non-Disclosure Agreement (NDA) between Fluke and the Supplier early in the relationship.

Fluke information such as drawings, materials used, technology, customers, and financial information are proprietary information. As such, the Supplier will not

divulge the information to other parties. Drawings of parts designed by Fluke are

exclusive intellectual property, and as such, the Supplier should not manufacture parts from these drawings for any purpose or party other than for Fluke.

3.3 COMMUNICATION

In conjunction with the Fluke factory and Supplier, the Fluke Commodity Manager will define the appropriate communication channel at the commencement of the relationship. The Fluke Commodity Manager is responsible for communications regarding:

- Price changes.
- Multiple Fluke factory quality/delivery issues.
- Contractual changes.
- The Fluke Commodity Manager will be accountable for providing the Fluke Supplier Quality Manual to the Supplier and organizing quality audits.
- All instructions must be confirmed in writing. A Fax or email is considered an acceptable form of written communication.
- Changes to the Fluke PO will be communicated via a written change notice such as a PO change.
- Acceptance of the PO should be delivered to the appropriate Fluke Commodity Manager or NPI Buyer.
- Supplier requests for any temporary deviations or permanent changes must be documented and forwarded to Fluke before the change is implemented. Fluke will review the submission and will provide a written response to the Supplier with an approval or rejection.
- Suppliers must communicate potential quality issues or late deliveries of product or components to Fluke as soon as the Supplier is aware of them. This communication can be verbal but must be confirmed in writing.

3.4 COST REDUCTIONS/IMPROVEMENTS

We expect Suppliers to proactively engage with Fluke to reduce costs on an ongoing/annual basis.

4. REFERENCES

- [ATEX CoC Template](#)
- [ATEX Requirements](#)
- [ATEX Supplier Acknowledgement of Understanding Form](#)
- [ATEX Supplier Evaluation Tool](#)
- [Fluke Appearance Standard](#)
- [Fluke Supplier Quality Manual](#)
- [FPQP Supplier Training](#)
- [FTV Supplier Code of Conduct](#)
- [FTV Supplier Evaluation Tool](#)
- [Packaging Handbook for Suppliers](#)
- [Supplier Acknowledgment of Understanding Form](#)
- [Supplier Deviation Form](#)

5. APPROVAL AND NOTIFICATIONS

- Approver: Process Owner, Supplier Quality Manager
- Approver: Director of Global Quality
- Approver: Quality Systems Manager
- Document Reviewer: Corporate Quality Council
- Document Owner: Supplier Quality Engineer

6. CHANGE HISTORY

The translated version of this document must be reviewed and revised each time this document is revised to ensure changes are easily identified for translation purposes.

<u>REV/ DATE</u>	<u>BRIEF DESCRIPTION OF CHANGE(S)</u>

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<p>Rev. 10 10/11/2023</p>	<p>Updated document signature and name; updated links; Section 1.1 Adding Janos statement; Added Section 2.1.1 Confidentiality and Intellectual Property; Added Section 2.1.2 Compliance with Applicable Laws and Regulations; Added Section 2.1.3 Records and Documentation; Section 2.7 clarification of the nonconforming material; Section 2.8 clarification of SCAR statement; Section 2.10.1 adding a paragraph including the link of PROCURE17 ATEX Requirements; Section 2.10.2 adding Regulatory Compliance section; Section 2.11 adding paragraph including the link of PROCURE16 Medical devices requirements; Section 2.12 adding Supplier packaging requirements including the link of QSD111.04 App.A Packaging Quality Manual for Suppliers; Section 3.1 Adding more items to be include in the RFQ and the links were updated, also adding ATEx and Medical device requirements links; Document was reviewed and some wording was updated or corrected; removed Section 3.5 Supplier Rating System; Added Section 4 References.</p>
<p>Rev. 011 04-Feb-2024</p>	<p>Updated links from Intellex system to PLM system.</p>