



TOPFLIGHT'S SUPPLIER QUALITY AGREEMENT

This Supplier Quality Agreement dated _____ is by and between Topflight Corporation, with office located at Glen Rock, PA, (hereinafter "Purchaser") and _____ doing business as _____, with offices located at _____ (hereinafter "Provider"; Purchaser and Provider are collectively referred to as the "Parties").

WHEREAS, Purchaser engages Provider in the manufacture of Product or provider of Services for use by Purchaser, on the terms and conditions set forth below;

WHEREAS, Provider desires to sell Items to Purchaser under the terms and conditions set forth in the quotations for Items, and below;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and agreements provided herein, the parties hereto, intending to be legally bound hereby, agree to adhere to or provide as follows as applicable to the product or service being provided:

QA-01 CERTIFICATE OF CONFORMANCE (C of C)

Manufacturer's and or Supplier's Certificate of Conformance is required at the time of delivery and must contain, at a minimum, the following:

1. Provider's name
2. The Purchaser's Purchase Order Number
3. Indicate conformance to the drawing/specifications,
4. Lot/Batch#, or serial numbers, as applicable
5. The Purchaser's part number with Revision level and expiration (if applicable).
6. If additional information is required, this shall be stated on the purchase order.

QA-02 CERTIFICATE OF ANALYSIS (COA)

Certificate of Analysis is required at the time of delivery, if requested. Material supplied shall be accompanied with a Certificate of Analysis (Test Report) indicating compliance with requirements of the material specifications and shall include, at a minimum, the following:

1. Provider's name,
2. The Purchaser's Purchase Order Number,
3. Indicate conformance to the drawing/specifications,
4. Lot/Batch#, or serial numbers, as applicable,
5. The Purchaser's part number with Revision level and expiration (if applicable),
6. Test data,
7. COA signed by the provider responsible employee and title of employee.
8. If additional information is required, this shall be stated on the purchase order.

QA-03 CORRECTIVE ACTION REQUEST (CAR) or SUPPLIER CORRECTIVE ACTION REQUEST (SCAR)

Provider shall provide documented corrective action response including the root cause on failures of product, or service on the purchaser supplied Corrective Action Request Form. Failure to perform an analysis, complete and



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return the CAR could result in seller disqualification. Due date for a response to any CAR or SCAR is noted on the relevant form.

QA-04 LOT TRACEABILITY/RECORDS

The provider must maintain lot and batch control for the products provided on the purchase order. Provider shall securely maintain records for the life of the medical device as communicated to your organization by The Purchasing Organization or a minimum of 7 years unless otherwise stated on the purchase order. The purchaser shall have right of access to these records if required.

QA-05 TESTING, INSPECTION DATA

Testing, inspection or manufacturing supporting data is required to be sent with the sample or manufactured product. Required information is stated on the purchase order.

QA-06 NONCONFORMING MATERIAL

Provider is required to notify the purchaser and obtain disposition authorization of any nonconforming product that is our property prior to or intended for delivery.

QA-07 CHANGE CONTROL

Provider shall not make changes to materials, processes, drawing requirements or control factors from those of which approval was based, unless changes are approved by the purchaser prior to implementation. Any of these changes must be requested to the purchaser purchasing department in writing, allowing sufficient time to evaluate the impact of the proposed change.

QA-08 SURVEILLANCE REQUIREMENTS

The purchaser, its customers and any applicable regulatory authorities maintain the right to review provider's inspection program, manufacturing processes, service providing facility including right of access to all facilities. These rights apply at any level of the supply chain.

QA-09 CONFLICT MINERALS

The provider is committed to complying with Section 1502 of the United States Wall Street Reform and Consumer Protection Act, also known as the U.S. Dodd-Frank Act. Therefore, The Purchaser requires all components and materials used in our products that contain "Conflict Minerals" (gold, tin, tantalum, and tungsten) must be sourced from "DRC conflict free" smelters. The Purchaser shall periodically request the smelter information of all conflict minerals from the supplier.

QA-10 FLOW DOWN REQUIREMENTS

The purchaser shall notify the provider of any special requirements, critical items or key characteristics that are required to be flowed down the supply chain. These requirements shall be stated on the purchase order when applicable.



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Requirements for test specimens shall be communicated to the provider through special notation on the purchase order when applicable.

When applicable, the provider shall be required to use the purchaser's customer-approved special process sources. These requirements shall be stated on the purchase order when required.

QA-11 FIRST ARTICLE INSPECTION

If a first article inspection using industry accepted tools and techniques is required for manufactured, assembled or tested product the requirement shall be stated on the purchase order.

QA-12 SAFETY DATA SHEET (SDS) (Formerly MSDS)

An SDS is required to be sent with the material or product, unless it is exempted from 29 CFR 1910.1200..

QA-13 CALIBRATION OF MONITORING AND MEASURING EQUIPMENT

The provider conducting calibration of monitoring and measuring equipment shall be ISO 9001 registered at a minimum. When specified on the purchase order the laboratory shall be accredited to ISO 17025 General Requirements for the Competence of Testing and Calibration Laboratories and have the specified equipment defined in their scope.

QA-14 QUALITY MANAGEMENT SYSTEM (QMS) SPECIAL REQUIREMENTS

Any special QMS requirements imposed by the purchaser shall be contained in the purchase order.

QA-15 SERVICE PROVIDERS

Service providers shall provide evidence of licensing and certification that are required in conformance with statutory and regulatory requirements.

By acceptance of Purchase Order, the Supplier accepts this Quality Agreement unless otherwise notified.

QA-16 SUPPLIER PERFORMANCE

Suppliers will be evaluated for Quality Performance. Suppliers that score less than 80% for lot acceptance will be placed on a Conditional status. A SCAR will be issued and an improvement plan must be submitted to Topflight within 90 days of being notified.



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Name

Name

Title

Title

Company Name

Topflight Corporation

Signature/Date

Signature/Date