

Title: Quality Policy Manual  
ISO 9001:2015  
ISO 13485:2016  
AS9100D:2016

**Document: Q1**  
**Revision: P5**  
**Date: 1/27/2021**

Protomatic Quality Manual Q1 Rev P5  
APPROVED.docm

Original Approval  
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QA Approval  
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*PROTOMATIC*



## Quality Policy Manual

WEB SITES:

[www.Protomatic.com](http://www.Protomatic.com)

[www.ProtomaticMedical.com](http://www.ProtomaticMedical.com)

[www.ProtomaticAerospace.com](http://www.ProtomaticAerospace.com)

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## Text Color Chart

**ISO 9001-Black**

**ISO 13485 Blue**

**AS9100-Red**

## Title, Scope and Field of Application

### Forward

#### 0.1 General

Protomatic, Inc. has adopted the ISO 9001:2015 Standard as its base quality management system but has also added the additional requirements of ISO 13485:2016 and AS9100D:2016. This decision is reflected in this manual. This document specifies the quality management and related systems that we use. Differences from the base are:

**ISO 13485 standards highlighted in Blue**

**AS9100 standards highlighted in Red**

The systems requirements of this manual are aimed at achieving customer satisfaction by consistently providing conforming product and meeting customer requirements through application of the system, continual improvement and the prevention of nonconformity. This Quality Manual conforms to the requirements and elements of the ISO 9001:2015 international standard. Protomatic, Inc. adheres to the policy statements defined for each Clause and sub-clause or element of the aforementioned standard, plus the added requirements. We are a prototype organization primarily serving the automotive, aerospace, and medical device fields but also providing Contract Manufacturing for all industries as we specialize with CNC Vertical Machining Centers, precision CNC Turning, welding, CAD, CAM, CMM, fixtures, and tool and die.

Certain specific requirements, such as those intended only for medical device manufacturers, that are stated in this manual are only met for the intended specific customer base and are noted accordingly.

The processes within Protomatic, Inc. are inter-related and this can be seen by the flow chart diagrams on page 11 of this manual as well as the inputs and outputs listed on all documented procedures, which we have created.

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## 0.4 Introduction to the Organization

### Company Profile

Protomatic Inc. is a Prototype machining and custom Short-Run Production CNC Mill and Turning Job Shop located in Dexter, Michigan, in a temperature controlled 30,500 square foot facility.

Protomatic offers, prototype, production manufacturing and assembly of custom parts and systems manufactured for Medical, Automotive, Military, Electronic, Aerospace, and Optical OEMs.

Knowledgeable with a variety of materials such as:

Aluminum, Magnesium, Brass, Phosphor Bronze , Aluminum Bronzes, Steels  
 Stainless Steels; 300 Series, 400 Series , Duplex, 17-4PH (630), MO 13-8PH,  
 Titanium; 6Al4V Grade 5, Ti pure Grade 2, 6Al4V ELI Grade 23  
 Plastics; Ultem™, Telfon™, UHMW, Delrin™, Acetel, Vespel™, Nylon, Kapton™, and others  
 Refractory Metals such as Tungsten, Niobium, Tantalum, Rhenium (Rene), Molybdenum, Super  
 Alloys; Haynes 25™, Kovar™, Invar™, Inconel™, Hastelloy™, Cobalt Steels and Nickel Steels.

Contract Manufacturing for all industries specializing with CNC Vertical Machining Centers, precision CNC Turning, welding, CAD, CAM, CMM, fixtures, and tool and die.  
 Custom parts made from billet or custom casting are available.



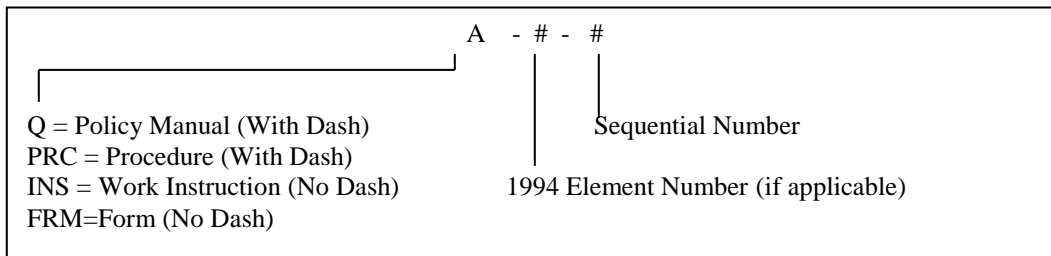
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### Quality Manual Control

Protomatic, Inc.'s Quality Manual is distributed on paper in a controlled fashion, with very few printed copies. The manual is reviewed periodically and approved by our General Manager or President. One controlled paper copy of this manual is accessible on the shop floor to view. The controlled electronic copy of the manual is stored in the network server and is accessible by limited authorized personnel and can only be modified by personnel the Quality Manager and/or the General Manager authorizes and requires re-approval by the General Manager or President. Uncontrolled versions of the Quality Manual are available to customers upon request. The distribution list on the previous page describes locations of "controlled" copies. Individuals listed in the Responsibility Matrix as primarily responsible for each policy had input in the creation of the policies listed throughout the manual. The General Manager or higher of Protomatic, Inc. approves the entire manual.

Quality Documentation Scheme- Protomatic, Inc.'s Quality documentation is numbered under the following scheme.



Q1 Quality Policy Manual (entire manual is controlled as one document)

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## Our Policy Statement

### QUALITY POLICY

Protomatic, Inc. will continuously improve its products and production processes to better satisfy the needs and expectations of its customers. Protomatic, Inc. is dedicated to on time delivery of defect-free products.

President: *Rita Wetzel*

This policy has been formulated and is endorsed by the President of Protomatic, Inc. The policy is explained and discussed at the general orientation training given to all existing and new employees. The policy is also posted in conspicuous locations throughout the company. Protomatic, Inc.'s Primary Objectives and Goals are also explained and discussed. They are:

*To always deliver On-time:* On-time Delivery allows customers to meet their scheduling commitments. Protomatic, Inc.'s timely delivery, in support of customer schedules, is mutually beneficial.

*To provide fast "Turn-around":* Short lead times are a significant strategy of Protomatic, Inc. Providing short lead-time products are an exceptional service and value to customers.

*To always deliver Defect Free Products:* Delivering defective products is extremely costly. Some costs include: direct product replacement costs, scheduling costs -"ripple effect" in manufacturing, customers missing schedule deadlines and/or Protomatic, Inc. loss of customer. Eliminating and/or controlling defective products is of paramount concern to Protomatic, Inc.

*To Exceed Customer Expectations:* Protomatic, Inc. strives not only to meet customer expectations, but also to exceed them. Protomatic, Inc. strives to always supply timely products at a price consistent with the most competitive technology available.

## Our Mission Statement

Slogan/ Tag Line: "Life-Saving Precision"

Protomatic is a CNC contract manufacturer with consistently high quality and uncompromising precision essential to produce our customer's components that save lives.

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## ***Protomatic's*** **Conflict Mineral Statement**

Protomatic Inc. endeavors to not purchase any material that contains "conflict minerals" which directly or indirectly finance or benefit armed groups in the DRC or an adjoining country. We are implementing reasonable due diligence processes to understand where "conflict minerals" are being used in our products and to determine the source and the origin within our supply chain.

Suppliers of tin, tungsten, tantalum and gold to Protomatic are expected to establish their own conflict minerals policies in conformance with the Dodd-Frank Act, due diligence frameworks and management systems that are designed to prevent conflict minerals originating from the DRC or an adjoining country, to the extent that they benefit groups committing human rights violations, from being included in the products sold to Protomatic. In the event Protomatic determines that a supplier has failed to develop and implement reasonable steps to comply with this Policy, Protomatic reserves the right to take appropriate actions per our quality systems procedure Purchase Order PRC-06-02 and Purchasing Requirements Instruction INS0602, which may include discontinuing the business relationship with the supplier.

## ***Protomatic's*** **Counterfeit Product Mitigation**

Protomatic, Inc. recognizes that the counterfeiting of components is a serious problem and affects the economy worldwide. The impact of counterfeit parts cannot be understated - these parts adversely affect the U.S. supply chain by greater costs to companies having to mitigate the risk, replace failed parts, lost sales and lost brand value, as well as damage to the business image. To customers, it means failed products, lower reliability and safety concerns.

Protomatic is committed to provide high quality products on which our customers may rely. In that endeavor, it is our policy and commitment of Protomatic Inc. to ensure that counterfeit parts are not used in the manufacture of Protomatic products per our quality system procedure PRC-06-02 and Instruction INS0602.

We purchase components directly from:

- Manufacturer Direct (OCM)
- Manufacturers Authorized Distributor
- Manufacturers Approved Agent/Rep

The performance of our approved vendors is continuously monitored, internally, by Protomatic, in addition to auditing by outside agencies, in accordance with the ISO 9001, ISO 13485 and AS9100 standards.

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## *Protomatic* Safety and Health Policy

**Company policy:** It is the policy of this company to ensure a safe, healthful workplace for all its employees. Injury and illness losses from incidents are costly and preventable. This company will employ an effective accident and illness prevention program that involves all its employees in the effort to eliminate workplace hazards.

**Management:** Management is accountable for preventing workplace incidents, injuries and illnesses. Management will provide top-level support of safety program initiatives. Management will consider all employee suggestions for achieving a safer, healthier workplace. Management also will keep informed about workplace safety and health hazards, and it will regularly review the company safety and health program.

**Supervision:** Supervisors are responsible for supervising and training workers in safe work practices. Supervisors must enforce company safety rules and work to eliminate hazardous conditions. Supervisors shall lead safety efforts by example.

**Safety Officer:** The safety officer or any employee representatives may recommend safety and health improvements in the workplace. The officer is responsible for identifying hazards and unsafe work practices, removing obstacles to incident prevention and helping the company evaluate the accident and illness prevention program.

**Employees:** All employees are expected and encouraged to participate in safety and health program activities including the following: reporting hazards, unsafe work practices and accidents immediately to their supervisors or a safety committee representative; wearing required personal protective equipment; and participating in and supporting safety committee activities.

## *Protomatic* Cyber Security Policy

**Company policy:** It is the policy of this company to ensure a safe cyber environment. This involves training employees on security principles. Steps are taken to protect information, computers and network from cyber attacks through the following methods; provide a firewall security for employees Internet connection, control mobile device usage, make backup copies of important business data and information, control physical access to computers, create user accounts for each employee, secure Wi-Fi networks, employ best practices on electronic payments, limit employee access to data and information, limit authority to install software and utilize password and authentication protocols. The company will measure and monitor effectiveness to improve overall security. Protomatic uses NIST SP800-171 as the principle guidelines, additional guidelines will be instituted subject to new threats. These guidelines may change without notification.