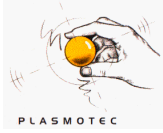


# QUALITY MANUAL

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**Revision: 11**

**Date: 11th August 2014**



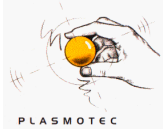
# QUALITY MANUAL

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BS EN ISO: 9001:2008

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3	Quality Objectives	5.4.1
4	Control, Distribution, Communication and Access to the Manual and Quality Documentation	4.2.3 + 4.2.4 + 5.4.2 + 5.5.3
5	Company Structure	5.5.1 + 5.5.2 + 5.5.3
6	Job Descriptions	5.5.1 + 5.5.2
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8	Quality System	4.2.1
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12	Product Identification and Traceability	7.5.3
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14	Inspection and Testing	7.1 + 8.1
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16	Inspection and Test Status	7.5.3
17	Non-Conformities, Corrective and Preventative Action	8.3 + 8.5.2 + 8.5.3
18	Handling, Storage, Packaging, Preservation & Del	7.5.1 + 7.5.5
19	Internal Quality Audits	8.2.2 + 8.2.3
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.....  
Managing Director



## QUALITY MANUAL

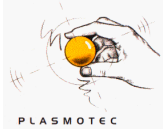
### 1.0 **INTRODUCTION TO THE COMPANY**

Plasmotec was established in 1989 and produces injection moulded products for a range of industries. We have invested in machines and technology enabling us to stay ahead of the competition bringing new ideas and products quickly and cost effectively to our customers.

Considerable investment has been made in the latest moulding equipment and the provision of a clean light production environment. The control of costs throughout the Company, and focus on the minimisation of the total costs of a project over its lifetime, commensurate with the demands on the product together with a quality philosophy and detailed inspection checks throughout, ensure Plasmotec mouldings reach the customer in good condition, fit for purpose and at a competitive price.

We believe in customer care and a comprehensive service and the provision of what the customer wants on time and in full. With approximately 30 moulding machines from 22 to 100 tonne lock many with programmable electronic control operated on a 24-hour basis provides flexibility and capacity for the production of thousands or millions of mouldings. Straight forward to highly complex technical components are produced in most mouldable commodity and engineering materials.

Products may be decorated with customer logos using conventional pad print techniques. Facilities are also offered for secondary operations including light assembly and automated assembly.



## QUALITY MANUAL

### 2.0 **QUALITY POLICY**

Plasmotec was established in 1989 and produces injection moulded products for a range of industries.

It is the objective and policy of Plasmotec Ltd to provide customers with mouldings that meet or exceed their expectation with regards to quality, on time and in full, that are fit for purpose, within the overall regulatory framework and at a competitive price.

In order to achieve the above, the Company has developed a Quality System which complies with the requirements of BS EN ISO 9001:2008.

The Quality System is supported and endorsed by every employee within the Company and is a reflection of our desire to provide our customers with the highest standards.

The Directors have the responsibility for co-ordinating the Company's Quality Management System ensuring all performance data and quality planning is reviewed at the Management Meeting. The Directors will implement specific checks including vigilance systems and audit routines as necessary, in order to provide feedback information and will instigate preventative and corrective action as required. This will include a review of any external audits by recognised bodies, which will include any conducted by our clients.

The Company complies with, and fully supports all Health & Safety Legislation.

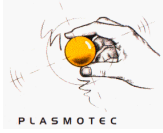
### 3.0 **QUALITY OBJECTIVES**

It is the objective of Plasmotec Ltd to: -

- To provide customers with products that meet or exceed their expectation with regards to quality on time and in full, that are fit for purpose and within the overall regulatory framework and at a competitive price.
- To maximise our efficiency and profitability by consistent monitoring of all relevant stages of our processes and services to assist in highlighting possibilities of non-conformance and to provide a basis for continuous improvement.

LAURENCE HIBBLE

MANAGING DIRECTOR



## QUALITY MANUAL

### 4.0 **CONTROL, DISTRIBUTION, COMMUNICATION AND ACCESS TO THE MANUAL AND QUALITY DOCUMENTATION**

4.1 The Quality Manual, Quality Procedures Manual and Flow Charts and other Quality documentation are maintained in electronic format in the computerised Quality Document Index. Access is controlled by means of user permissions that may only be set or changed by authorised personnel. All employees are given easy on line access to the documentation that is relevant to them. All documents are given unique identification references to include revision numbers. All documents are dated to show the date of issue or when last amended as appropriate.

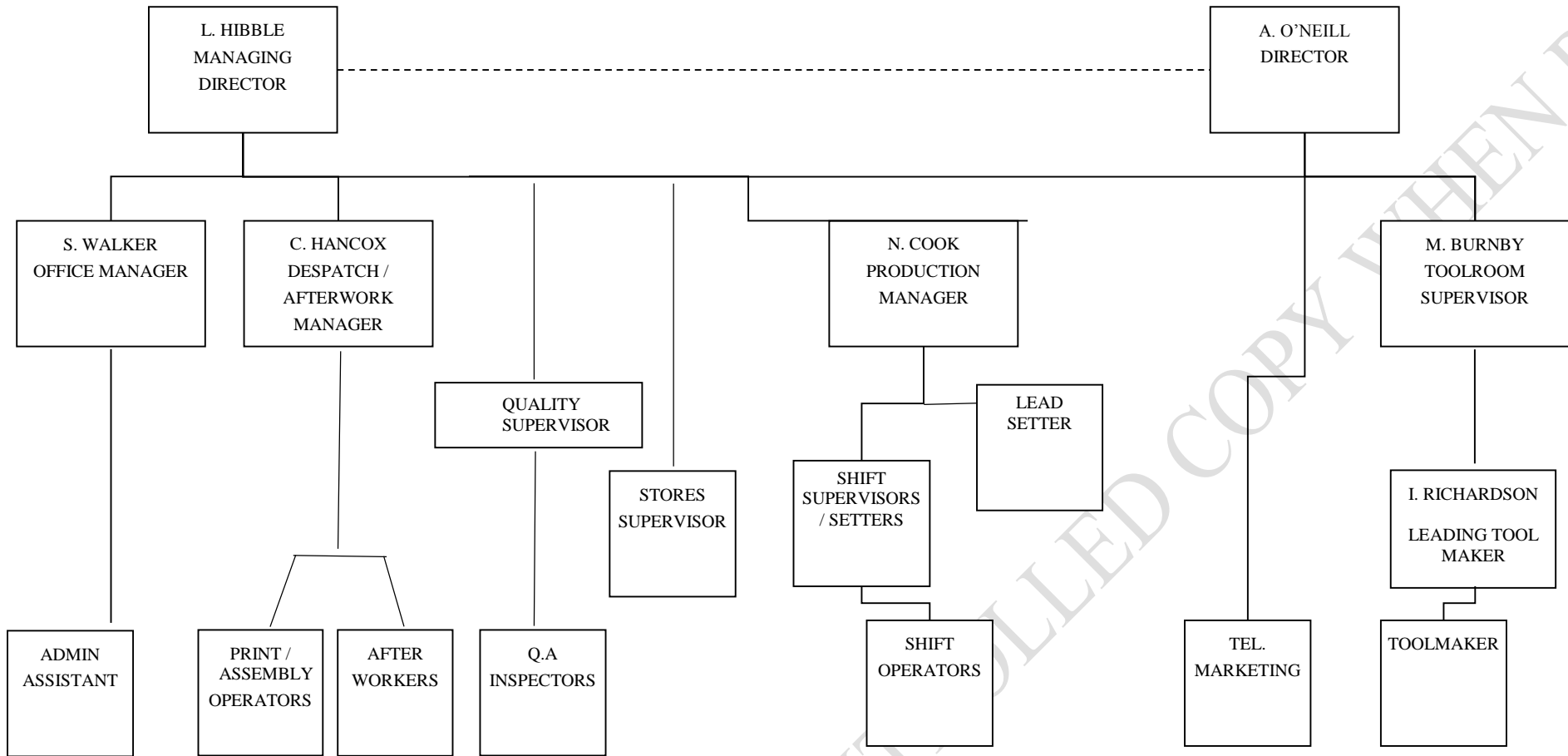
Physical copies of the manual are only issued in "uncontrolled" status.

4.2 The Company is pro-active in the provision of training and one of the objectives of such training is to ensure that relevant employees are fully aware and familiar with their responsibilities and their duties. This includes ensuring such training addresses the content of relevant Quality Documentation.

#### **Supporting Procedures:**

- PL 04 MANAGEMENT CONTROL

5.0 Company Structure



## 6.0 **JOB DESCRIPTIONS**

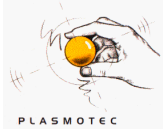
- 6.1 Each employee should receive a job description shortly after commencing employment and before they complete their probationary service. The job description should be signed by the Managing Director or nominated deputy such as the employee's manager or supervisor and by the employee.
- 6.2 Job descriptions may need to be updated from time to time to reflect significant changes in duties and responsibilities.
- 6.3 A signed job description should be completed and signed as per the above before an employee can complete his or her probationary period.

## 7.0 **MANAGEMENT REVIEW**

- 7.1 A meeting takes place at least once a year to review the Company's Quality Systems. An agenda for the meeting should be prepared prior to the meeting and so as to cover all of the topics detailed in the management review section of the procedures.
- 7.2 Any disclaimed areas are discussed as part of the management meeting under the section covering the Company quality system at least once a year.

### **Supporting Procedures:**

- PL 04 MANAGEMENT CONTROL



## QUALITY MANUAL

### 8.0 **QUALITY SYSTEM**

The documented Quality System is based on a three tier system:

- The Quality Assurance Manual
- The Quality Procedures Manual
- Flow charts

The Quality Procedures Manual consists of the following procedures:

- 01 Sales and Pre-Production
- 02 Purchasing
- 03 Production Control
- 04 Management Control

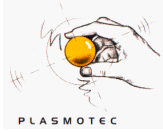
All of the above are made available to all appropriate staff on line.

- 8.1 A list of standard forms and documentation used within the system are held in the QA Document Index held in the Company's computer system.
- 8.2 The co-ordination of the Quality System is the responsibility of the Managing Director.
- 8.3 The Company formally reviews any significant changes to the quality system at the management review meeting. This review considers the need for any modifications and / or additions to the Company's quality system.
- 8.4 The company will ensure adequate resources are available in order to ensure the quality system requirements can be implemented, maintained and continually improved in order to further its effectiveness and ability to enhance customer satisfaction.

#### **Supporting Procedures:**

- PL 01 Sales and Pre-Production
- PL 02 Purchasing
- PL 03 Production Control
- PL 04 Management Control





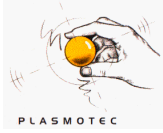
## QUALITY MANUAL

### 9.0 **CONTRACT REVIEW**

- 9.1 It is the responsibility of the Directors and Technical Sales to arrange for all quotations to be made taking into account the resources and capabilities of the Company.
- 9.2 When an order is accepted all requirements are recorded, authorised and validated prior to production.
- 9.3 The customer's requirements are reviewed against the specification and any variances are resolved prior to the commencement of production. During the production process, if any significant change is identified it must be authorised and where necessary a new specification is agreed with the customer. The Technical Director or nominated deputy is responsible for obtaining authorisation for any amendments.
- 9.4 The Office Manger or authorised deputy is responsible for actioning any amendments to the original order.

#### **Supporting Procedures**

- **PL 01 SALES AND PRE-PRODUCTION**
- **PL 02 PURCHASING**
- **PL 03 PRODUCTION CONTROL**
- **PL 04 MANAGEMENT CONTROL**



## QUALITY MANUAL

### 10.0 PURCHASING

#### Supporting Procedures

- PL 02 PURCHASING
- PL 03 MANUFACTURING CONTROL
- PL 04 MANAGEMENT CONTROL

### 11.0 CUSTOMER SUPPLIED PRODUCT

#### Supporting Procedures

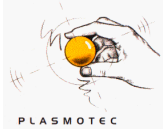
- PL 02 PURCHASING
- PL 03 PRODUCTION CONTROL

### 12.0 PRODUCT IDENTIFICATION AND TRACEABILITY

- 12.1 All materials and master batches are allocated unique reference numbers that identify them. These reference numbers are used throughout the Company. Material and colour reference numbers are used throughout the Company's purchasing processes and stores areas and processes and to identify what materials can be used to produce any given product.
- 12.2 Job Cards pull together what is required, what is manufactured, when and how and by using what materials and ingredients. Material and masterbatch batch numbers are recorded on job cards as used.
- 12.3 Job cards are retained in both physical and computer format for traceability at a future date.
- 12.4 Material and masterbatch batch numbers for each delivery are posted to the PDMS computer purchase order on receipt.
- 12.5 All mouldings produced are labelled as each batch is completed.
- 12.6 All finished product is labelled as part of the weigh counting process so as to enable traceability to originating job card

#### Supporting Procedures

- PL 01 SALES AND PRE-PRODUCTION
- PL 02 PURCHASING
- PL 03 PRODUCTION CONTROL
- PL 04 MANAGEMENT CONTROL.



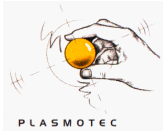
## QUALITY MANUAL

### 13.0 **PROCESS CONTROL**

13.1 The various processes involved in fulfil customer orders are shown and related and summarised in the Overall Flow Chart. This overview shows each key process (each Flow Chart) undertaken by the Company.

#### **Supporting Procedures**

- **PL 01 SALES AND PRE-PRODUCTION**
- **PL 02 PURCHASING**
- **PL 03 PRODUCTION CONTROL**
- **PL 04 MANAGEMENT CONTROL.**



## QUALITY MANUAL

### 14.0 **INSPECTION AND TESTING**

#### 14.1 **RECEIVING INSPECTION**

14.1.1 All incoming materials are checked in by the Stores Supervisor or Afterwork Despatch Manager or deputy by reference to delivery documentation and purchase orders which identify both quantity and other relevant information.

14.1.2 The level of inspection is determined by the accepted capabilities of the supplier used in accordance with their status in the Approved Supplier Register.

#### 14.2 **FIRST OFFS**

14.2.1 First Off Inspections are undertaken on all manufactured product.

#### 14.3 **IN-PROCESS INSPECTION**

14.3.1 During the manufacturing process the Operators and Quality Controller perform In Process Inspections.

#### 14.4 **FINAL AUDITS**

14.4.1 Some products may be subject to specific final auditing. Details are held in the Product Information Record.

#### 14.5 **LAST OFFS**

14.5.1 Last Off Inspections are undertaken on all manufactured product.

### **Supporting Procedures**

- **PL 01 SALES AND PRE-PRODUCTION**
- **PL 02 PURCHASING**
- **PL 03 PRODUCTION CONTROL**
- **PL 04 MANAGEMENT CONTROL**



## QUALITY MANUAL

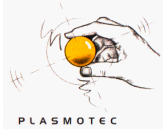
### 15.0 **CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT**

PL 03 PRODUCTION CONTROL

#### **Supporting Procedure**

- **PL 03 PRODUCTION CONTROL**

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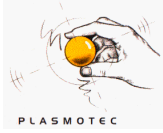
## QUALITY MANUAL

### 16.0 **INSPECTION AND TEST STATUS**

- 16.1 The Company's policy is to only use materials or products of an acceptable quality in the production process. All materials are subjected to Goods Inwards Inspection by the Stores Supervisor, or deputy and can only be released to the Factory if inspection has been satisfactory.
- 16.2 Non-Conforming products are marked with tape and stored separately.
- 16.3 All manufacturing is inspected, on completion of each process, by the operator. The next stage of process is commenced only if the Operator is satisfied with the standard of the preceding operation.
- 16.4 The status of the product undergoing quality control inspection is evident by reference to the in process inspection record, which remains with the product throughout the manufacturing process.

#### **Supporting Procedures**

- **PL 02 PURCHASING**
- **PL 03 PRODUCTION CONTROL**



## QUALITY MANUAL

### 17.0 **NON-CONFORMITIES, CORRECTIVE AND PREVENTATIVE ACTION**

- 17.1 All non-conformances identified in any process and snags addressing issues of process improvement are recorded using the Snag Report System and monitored by the Quality Controller and Directors. The Snag system holds all details concerning corrective and preventative actions required and undertaken. There is no exclusion to what may constitute a Snag.
- 17.2 Where necessary the corrective action will include the notification of the regulatory authority and the supplier of reportable incidents

#### **Supporting Procedures**

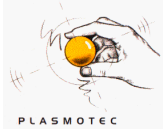
- **PL 01 SALES AND PRE-PRODUCTION**
- **PL 02 PURCHASING**
- **PL 03 PRODUCTION CONTROL**
- **PL 04 MANAGEMENT CONTROL**

### 18.0 **HANDLING, STORAGE, PACKAGING PRESERVATION AND DELIVERY**

- 18.1 All materials received into the Company including 'free issue' items are subject to receiving inspection by the Stores Supervisor or Afterwork Despatch Supervisor or deputy and stores in identified locations.
- 18.2 All finished mouldings are identified with a label showing, amongst other things, the job card and part number and stored in the appropriate storage racks if not for immediate despatch.
- 18.3 The nature of the products processed is such that they do not have in general terms a limited life span.
- 18.4 All products are packaged using approved materials and standards as detailed on the job card. Approved carriers (if applicable) being responsible for deliveries.

#### **Supporting Procedures**

- **PL 01 SALES AND PRE-PRODUCTION**
- **PL 02 PURCHASING**
- **PL 03 PRODUCTION CONTROL**
- **PL 04 MANAGEMENT CONTROL**



## QUALITY MANUAL

### 19.0 **INTERNAL QUALITY AUDITS**

19.1 The yearly audit plan is planned, controlled and administered by the Managing Director and the Support Services Manager. The audit programme is planned to take into consideration the priorities and importance of each quality procedure in relation to the needs of the business. The audit program should also focus on new processes or modifications to the process and areas of weakness.

#### **Supporting Procedures**

- **PL 04 MANAGEMENT CONTROL**

### 20.0 **TRAINING**

20.1 It is Company policy to continually monitor the training needs and requirements of all staff. The training needs and achievements of all Company staff are recorded and reviewed by senior management using the Computerised training records held in the Company's PDMS. Additional internal training is generated as and when required by the Support Services Manager and Managing Director. Wherever practicable, training undertaken should be verified by appropriate means.

#### **Supporting Procedure**

- **PL 04 MANAGEMENT CONTROL**





## QUALITY MANUAL

### 21.0 **SERVICING**

21.1 Servicing is not appropriate for the control of the Company's operation.

### 22.0 **STATISTICAL TECHNIQUES**

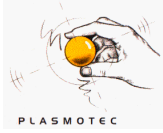
22.1 Statistical techniques have been discussed by the Senior Management and are not appropriate for the control of the Company's production.

### **Support Procedure**

- **PL 01 SALES & PRE-PRODUCTION**
- **PL 03 MANUFACTURING CONTROL**

### 23.0 **Excluded Areas**

Design and Development of Plastic Moulded Components



## QUALITY MANUAL

### 24.0 REFERENCE PROCEDURE

#### PL 01 Sales and Pre Production

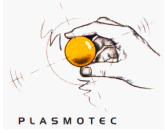
*Sales Prospecting*  
*Processing Sales Orders New Customers / New Products*  
*Basic Drawing Production*  
*Technical Review*  
*Schedule Production*  
*Raising, Processing and Allocating Job Cards*  
*Invoice and Credit Notes*  
*Carriage*  
*Raising Certificates of Conformity*  
*Customer Complaints*

#### PL 02 Purchasing

*Supplier Approval*  
*Control of Suppliers*  
*Purchasing*  
*Ordering / Control of Sample Materials*  
*Manual Purchase orders*  
*Verification of Purchased Product*

#### PL 03 Production Control

*Mould Tool Build Process*  
*New Product Introduction*  
*Customer Approval Procedure*  
*Printed Product Introduction*  
*Gauging Requirements*  
*Special Concessions*  
*Rework*  
*Factory Product Allocation*  
*Machine Set Up*  
*Process Inspections*  
*Rejects Control*  
*Afterwork*  
*Outwork Controls*  
*Production Quality and Efficiency and On Time In Full*  
*Storage Control*  
*Batch Traceability*  
*Tool Maintenance and Storage*  
*Storage of Finished Products and Materials*  
*Customer Supplied Product*  
*Release of Finished Products and Material Changes*  
*Parts for Return to the Supplier*  
*Despatch*  
*Print Production Controls*  
*Calibration and Gauge Control*



## QUALITY MANUAL

### PL 04 Management Control

*Quality Records*  
*Document and Data Control*  
*Non-Conformities*  
*Internal Quality Audit & Review*  
*Advisory Notes Recall*  
*Training Requirements*  
*Management Quality Review*

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