purple surgical

UNCONTROLLED WHEN PRINTED OR ELECTRONICALLY DISTRIBUTED

Quality Assurance Site Master File:

Issued By: Jason Howes Approved By: Adam Lusby Issue Date 10/07/2013 Amendment Record DCN: **490**

QA & RA Manager
Purple Surgical

Production Director
Purple Surgical

SM01 Issue: 004

1.0 Table of Contents:

2.0 Distribution.

This document is intended for special distribution to:

Jamjoom

Date of Distribution: **29/07/2013**

Upon distribution this document becomes Uncontrolled and is for Reference only.
A controlled master document is held on file at Purple Surgical. This document is subject to regular reviews, and where appropriate is subject to updates.

3.0 Change Control.

Revision changes will be identified by endorsement of a unique Document Change Note number in the footer of each page of this document. The revision No is applicable to the details upon the page it has been applied to. Specific details of the revision will be held on for reference at Purple Surgical.

4.0 Company Overview and Contact Addresses.

Purple Surgical has a 55,000 sq ft manufacturing facility based at Culmhead Business Centre, Culmhead, Taunton, Somerset, TA3 7DY. UK.
Telephone: 01823 601001. Fax: 01823 601400.

Purple Surgical has a head office facility based at, 2 Chestnut House, Farm Close, Shenley, Hertfordshire. WD7 9AD.
Purple Surgical Telephone: 01923 839333 Fax: 01923 839444

4.1 Organisation charts

***** Refer to Attachments for Manufacturing facility and Head office**

4.2 Operational Workforce Details.

Operational Area	No employed	Location
Production	70	Manufacturing Facility
QA / QC	5	Manufacturing Facility
Goods In/Out, Warehousing & Logistics	9	Manufacturing Facility
Sanitation	2	Manufacturing Facility
Maintenance & Engineering	2	Manufacturing Facility
Management & Administration	8	Manufacturing Facility
Projects Engineer	1	Manufacturing Facility
Sales & customer services	24	Head Office
Management	2	Head Office
Accounts	1	Head Office
Marketing	2	Head Office

5.0 Manufacture.

5.1 **Scope of manufacture.**
Injection moulding, extrusion, assembly, packaging, sales and distribution of sterile and non-sterile single use and re-usable medical devices.
Manufacture, sales and distribution of sterile and non-sterile products used within the medical environment.

5.2 **Key Production Equipments.**
The following table defines KEY equipment used by the company in order to provide and maintain the current scope of supply.

Equipment	Products / services supported	Location.
Tube Extruders Qty 3	Manufacture of plastic tubing	Manufacturing Site
Injection Moulders Qty 8	Plastic connectors/adaptors/devices	Manufacturing Site
Automated Pad Printer	Ink Printing machine for devices	Manufacturing Site
Automated blister packaging machines Qty 4	Manufacture of primary packing pouches and automated control of the packing process.	Manufacturing Site
In line thermal printers Qty 4	Automated printing devices used in connection with blister packaging machines	Manufacturing Site
Label printers Qty 3	General industrial label printers used to generate packing and product labels.	Manufacturing Site
Production assembly fixtures Multiple	Assembly & manufacture of specific devices	Manufacturing Site
Warehouse management system	Business managements system for warehousing and Logistics control	Manufacturing Site
Business control Software	MRP II level software for business process management	Head Office
Mainframe IT server module	Electronic data storage, control and distribution.	Head Office

In addition to the equipments listed above, are numerous process specific tools and equipments utilised for manufacture, assembly, inspection, calibration and maintenance requirements.

In order to ensure process performance, capability and non-interruption of supplies, the companies processing equipment and support services are monitored, maintained, serviced, backed up, and/or reviewed at a frequency as is appropriate to ensure their continued suitability and reliability.

5.3 **Controlled or Hazardous substances.**

Process consumables/materials
There are 4 controlled substances/chemicals which are utilised in production processes, namely:

- Cyclohexanone (glue)
- Silicone oil (lubricant)
- Dichloromethane (stretcher)
- Isopropanol (alcohol)

These items are subject to controlled storage and controlled identification during usage, however do not represent risk in their product application.

Products
Infrequently some products and equipments can be received from head office after medical trial or usage. These are normally returned to assist product function reviews or investigations.
In such cases the items returned are suitably packaged and identified as contaminated samples. Specific procedural controls regarding handling, segregation from production environments and safe disposal / sanitation apply under these circumstances so as to eliminate the risk of cross contamination.

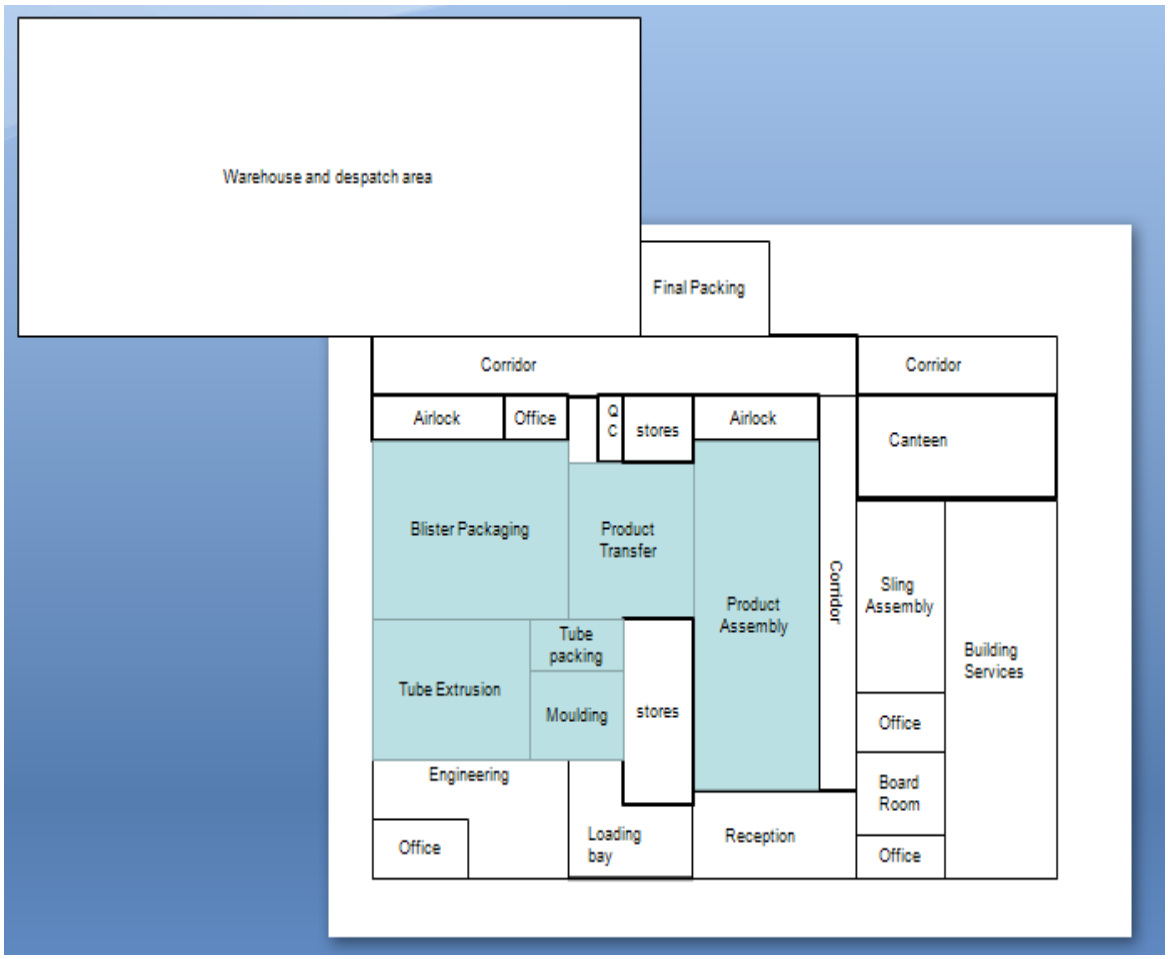
5.4 **Procured/Subcontracted services.**
Purple Surgical procure the following key services to support manufacture and delivery:

- Raw materials and finished goods items to support in house manufacture.
- Laboratory assistance for microbiology analysis needs.
- Product Sterilisation services.

6.0 Facilities and Plant.

6.1 Buildings and layout.

The manufacturing facility is housed within a 55,000 square ft brick and aluminium clad building.
Areas within the manufacturing facility are designated as either controlled or uncontrolled working environments, dependant on the nature of activities performed within.
Works performed in controlled environments are subject to strict controls surrounding, protective work attire, hygiene, health monitoring, access restrictions, sanitation, and facility services monitoring and upkeep.
A schematic of the facility is outlined below, with shaded sections identifying controlled areas.



6.2 Surrounding area.

The company occupies part of a rurally located business park.
The area surrounding the business park is in the main agricultural land used for the rearing of livestock and growing of crops.

6.3 Adjacent business and property.

Within the business park are 4 other businesses.
The nature of business in adjoining properties relates to:
Offices, light mechanical engineering, light industrial fabrication and computer/peripheral services.

6.4 **Sanitation control**

Procedural controls relating to the use of clean room clothing, personal hygiene, and restrictions on transportation of goods and effects are in place for activities performed in designated controlled environments.

The design of the controlled area environments incorporate facilities for cleansing of the intake air via heppa filter. The cleaned air is force ceiling fed into work environments and single pass extracted at a lower rate so as to generate a positive pressure in the controlled work environments. This ensures external air supplies from uncontrolled environments do not migrate into controlled environments. A daily review of controlled area overpressures are monitored to ensure satisfactory system operation.

The work environments are also subject to a daily cleansing routine to ensure maintenance of a suitable working environment.

The effectiveness of company's sanitation processes are regularly monitored by the performance of environment based microbiology examinations, audits of air handling equipment performance (particle counts) and through audit of personnel sanitation control disciplines.

Chlorination and maintenance procedures are also in place to ensure control of processes that incorporate the use of water.

General water supplies used for personal hygiene controls are regularly monitored as part of the companies' microbiology examinations to ensure that the quality of supply is of a suitable standard.

6.5 **Critical Services.**

The company's manufacturing requirements are primarily dependent on electrical power, water supply and compressed air.

Direct services for power and water are supplied to site, and compressed air is generated on site. Reliability of all services is high, with minimal risk of non-continuity, or failure, of service as a result from local external sources.

6.6 **Maintenance.**

The company maintains its infrastructure and equipments in order to ensure continuity of both quality and service.

Preventive maintenance regimes are employed within the company and are supported by either, or a combination of, internal maintenance engineers or subcontracted service providers.

Wherever appropriate, critical equipments and tools are calibrated at frequent intervals to ensure accuracy during use.

7.0 Quality Management, Assurance and Control.

7.1 Quality Policy.

purple surgical

Quality Assurance

Quality Manual

Title	Quality Management System
Reference	5.3
Date	12/03/2013
Issue	4
Page	Page 1 of 1

Controlled Document

Quality Policy & Mission Statement

Our mission is to enjoy what we do & convey this sense of satisfaction, achievement & mutual benefit to all our existing & potential customers, by providing an essential service that is prompt & professional.

Our task is to keep moving forward in markets where technological advances are paramount & the demand for quality is ever evolving.

The Purple Surgical group is committed to manufacturing & distributing a wide range of high quality products to the UK & international markets, at very competitive prices.

It is our purpose to produce goods that meet the customer's growing needs & ensures their continued satisfaction.

The organisation is committed to compliance with & maintaining the effectiveness of the requirements outlined in the:

- ISO 13485 / CAN/CSA ISO 13485 & ISO 9001 Quality Managements System standards
- 93/42/EEC Medical Device Directive
- SOR/98-202 Canadian Medical Device Regulations

Procedures have been adopted & are defined in the company's Quality Manual.

These procedures have been laid down to cover all aspects of operations & it is mandatory that all personnel adhere to these requirements & observe the Good Manufacturing Practise as outlined in the company handbook.

The group operates a policy of continuous improvement through internal audits, customer liaison & post market surveillance, while quality objectives are established to highlight current issues which are accessed as part of the company's management review system.

7.2 **Accreditation Status:**
Purple Surgical has gained, and hold current, accreditation to the following recognised standards.
Electronic *PDF copies of current certificates are available upon request.

Standard	Certificate No	Applicable to	Issue date	Re-certification due date
93/42/EEC Annex II	GB02/58682	Purple Surgical	15/05/2012	15/05/2017
93/42/EEC Annex V	GB11/83845	Purple Surgical	15/05/2012	15/05/2017
ISO 13485:2003	GB04/62831	Purple Surgical	15/05/2012	15/05/2015
ISO 9001:2008	GB04/62809	Purple Surgical	15/05/2012	15/05/2015

7.3 Quality Assurance.
The companies are committed to ensuring that their products and services meet the needs and expectations of their customers. This is achieved through effective quality planning, control, review and improvement practices.
As outlined in section 7.2, the companies have adopted to work in accordance with certain recognised Quality Managements System models, which provide the framework for a Quality Assurance approach.

Company representatives for QA and Customer Service:

Quality Assurance and Regulatory Affairs Mgr	Mr. Jason Howes 01823 602043
Operations Manager	Mrs. Barbara Young 01923 289075
Customer Services Manager	Mrs. Jane Bradley 01923 289082

Common Quality Assurance methods employed, but are not limited to:

- Design studies, with customer involvement.
- Product function clinical trials.
- Packaging and labelling studies.
- Shelf life studies.
- Risk analysis and process validation
- Working environment controls.
- Provision and control of work instructions
- Training.
- Batch history traceability: recording and retention activities.
- Process output analysis, and corrective actions.
- Complaint handling and investigation methods.
- Pro-active feedback relations and post market surveillance activities, to ensure product satisfaction & identify opportunity for improvements.
- System audits.
- External audits by accreditation bodies.

7.4 Quality Control.

Product quality performance will be measured / assessed by the following QC activities:

- Material receipt inspections.
- 1st off manufacturing inspections.
- In process self inspection by operatives.
- Wandering Inspections.
- Packaging inspections.
- Finished product inspections.

Unless otherwise specified, QC inspections will be performed in line with ISO 2859-1 sampling procedures. General inspection levels are set for each activity dependant on the nature of the inspection and required level of control.

Process compliance will be measured assessed by the following QC activities:

- Scheduled microbiology examinations
- Calibration control
- Process audit

7.5 Validation.

In order to establish confidence in the capability of a process employed by the company, analysis of the process output, with consideration to its deign input or intended usage, is undertaken.

- The validation will occur at new product/process introduction stages.
- Process amendment stages.

In addition re-validation of a historic stable process may also occur based on a scheduled expiry period, or as part of a directed process audit.

The depth and detail of the validation process will be determined by the QA function based on Risk Analysis, FMEA or other appropriate QA tool.
Records of validation plans/results are held by the company in product specific files, or generic files- if the validation process surrounds multi-use equipments or environments. Similarly, resultant SOP's, and any subsequent process amendments, are retained by the company in the same manner. Examples of which are outlined below.

- Standard Operating Practices
- Operational tolerances and acceptance limits
- Maintenance processes, frequencies and post maintenance re-qualification.
- Calibration requirements, frequencies and acceptance limits.
- Sanitation processes, frequencies and acceptance limits

Certain aspects of process validations or analysis are part of a validation process, performed by the company requires specialist assistance. This primarily relates to Sterilisation and Microbiology.
The company approved service providers in these fields are outlined below.

With respect to sterilisation process validation and re-validation,
The company uses the services of: Isotron Laboratories, Wiltshire, UK.

With respect to microbiology assistance and bio burden testing, the company uses the services of: Sothern Microbiological Services limited, Somerset, UK

7.6 Human Resources and Training.

All staff employed by the company are subject to general induction and specific job function training. The majority of training can be facilitated by internal resources through the transfer of specific job application knowledge supported by Standard Operating Procedure guides. Where specific capabilities are required, specialist training assistance from outside service providers can be sought.

The effectiveness of employee skills, and that of the training provided, is undertaken by Team Leader and line Management functions.

Quality Assurance audit and investigation practices support the analysis, and where required, the improvement of HR capabilities.

Formal records of training are documented and retained in a controlled manner by the company for staff employed.

In the event of the need to utilise general contracted labour the same process applies.

In the event of the company requiring specialist contracted support, the contracted personnel working at the company will be fully briefed and trained in the fulfilment of company standard operating practices appropriate to the service they are providing, or work environment they will be operating within.

7.7 Non-Conformance and Complaint handling.

Any complaint received in relation to product or service quality will be recorded and reviewed in line with company complaint investigation procedures, and any applicable legislative requirements.

The company products are delivered with individual batch traceability lot identifiers, which provide traceability throughout the products manufacturing and delivery history. Manufacturing and supply records containing this traceability identifier are maintained by the company for a minimum of 6 years. These records provide sufficient information for the company to affect a product re-call if the need ever arose.

7.8 Storage and distribution integrity.

Products awaiting despatch are clearly identified by product labels on outer packaging.

The outer packaging is protected from potential floor level contamination sources via the use of pallets for elevated storage.

Products are distributed by company approved courier services, whose practices satisfy the needs of the company in respect of maintaining the integrity of the goods handled.

There are no current requirements for the use of specialised freight forwarders in respect of refrigerated services and/or specialist transportation controls.