

COMPANY OPERATING PROCEDURES Organisation SCOPE & Responsibilities VM3/COP/02

1. Scope

The design, outsource manufacture, manufacture and service (including that carried out on customer premises of nerve stimulators and nerve locators, resuscitators, monitoring devices for physiological parameters including accessories) of the following: Apgar timer; Gas Exchange monitors; Oxygen monitors; Oxygen Sensors; Pulse Oximeters; Pulse Oximetry sensors and cables; Temperature monitors; Temperature probes and cables including Temperature probes in catheters ; Cot lids; Gas respiratory adaptors; Gas respiratory valves; Heat shields; Nerve locators; Nerve stimulators; Oxygen hoods and tents ; Phototherapy light shields; Resusitators; Ventilation tube holders; Simulation, Test and Calibration Equipment for monitoring devices.

2. RESPONSIBILITIES

2.1 The Managing Director

The Managing Director has the ultimate responsibility for directing and co-ordinating all company policies and therefore for ensuring that appropriate systems and procedures are in operation for the success of the Quality Assurance Programme. He is the Management Representative as required by item 4.1.2.3 of *BS EN9001*, and is responsible for ensuring that everyone in the organisation accepts and meets their responsibilities for satisfactory quality attainment. He is responsible for ensuring that there are adequate resources and capable personnel to effectively carry out all necessary verification activities. He is responsible with the Financial Controller for Purchasing. He / she is responsible for insuring that there are adequate resources and capable personnel to effectively carry out all necessary process activities. He carries out Management

Reviews and Quality Audits. He is responsible for enquiries and quotations. He maintains the approved supplier file. He is responsible for the control and maintenance of the Quality and Procedures Manual and holds the Master copies.

He is also responsible for CMDCAS updates, and Licences.

Including Mdall product listings <http://www.hc-sc.gc.ca/dhp-mps/md-im/licen/mdlic-eng.php> submitting Certificate updates within 30 day.

2.2 Financial Controller

The Financial Controller is responsible to the Managing Director for all financial matters and also has the following quality duties:-

- a) Overall responsibility for processing customer quotations.
- b) The purchasing function.
- c) Carrying out quality audits (with the Managing Director).
- d) Controlling Supplier Documentation.

2.3 General Director

The General Director is responsible for directing and co-coordinating the day-to-day operations of the business, and therefore ensuring that all personnel abide by the dictates of the company Safety and Operating procedures. He / she is also responsible for the sales and purchasing functions. He / she will also, with the Managing Director, ensure that there are adequate resources available for the company to perform to its best capability

2.3

I.T. Director

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The I.T. Director is responsible for the company's software and hardware requirements, He / she is also responsible, together with the General Director, for the purchasing functions, and for ensuring that adequate resources are available.

2.4 Accounts Director

The Accounts Director is responsible, with the other Directors, for all the financial matters affecting the company. He / she is also responsible for the day-to-day running of the sister company "Vandagraph".

The Office Manager/Quality Administrator /Deputy to management representative

Office Supervisor

The Office Supervisor is responsible for the day-to-day internal sales functions, and general purchasing. He / she is also responsible for control of all dispatch processes affecting products and / or services.

The Office Manager/Quality Administrator is responsible to the Managing Director for:-

- a) Receiving, checking and entering on the computer all customer orders.
- Raising Invoice/Despatch Note Sets.
- b) Goods receiving procedure.
- c) Checking picked orders.
- d) Updating the stock book.
- e) Administration of customer complaints and the goods return procedure.
- f) Issue of credit notes.
- g) Arranging transport
- h) Issue into stores correctly if not requiring QA inspection.
- i) Updating outstanding stock either on S.R. or loan.
- j) Chasing outstanding payments.

2.4 The Technical Manager

The Technical Manager is responsible to the Managing Director for:-

- a) The Quality assurance function.
- b) The repair function.
- c) Maintaining up-to-date manufacturers or suppliers catalogues/technical data sheets.
- d) Investigating customer complaints/warranty claims and the recall of suspect product procedure.
- e) The Calibration procedure.

2.5 The Q.C. Engineers

The Q.C. Engineers are responsible to the Technical Manager for:-

- a) The Quality assurance function with regard to the inspection of incoming products for stock and the function and safety testing of repaired items.
- b) Controlling the work of the Technicians.
- c) Minor repairs of instruments.
- d) The writing of instrument check procedures and checklists.
- e) The issue into stores by correct location.
- f) The storage and identification of products.
- g) The quarantining of non conforming products.

2.6 Office Staff

Office Staff are responsible to the Office Manager for:-

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- a) Assisting customers with enquiries.
- b) Taking customer orders.
- c) Checking and raising invoice/despatch note sets and entering customer orders on the computer and/or in records.
- d) Picking, assembly and packing of orders.
- e) Receipt of goods.
- f) The clear identification and despatch of orders.
- g) Filing of documentation.

2.7 Engineers

Engineers are responsible to the Technical Manager for:-

- a) The repair and maintenance activity (with the Q.C.Engineer).
- b) Technical investigation of non conforming products.
- c) Customer complaints/warranty claims.
- d) Quality assurance of incoming product and after repair.
- e) Servicing of demonstration instruments.

2.8 Technicians

Technicians are responsible to the Q.C. Engineer for:-

- a) Quality assurance of incoming products requiring 'low level' testing.
- b) Quarantining and labelling non conforming products.
- c) Packaging, labelling, testing and placing products in the appropriate stock location.

2.9 Sales Personnel

The Sales Personnel are responsible to the Managing Director for:-

- a) Visits to customers/potential customers as necessary to assist and advise the customer on the use of Viamed products.
- b) Following up customer enquiries and quotations.
- c) Customer complaints and minor repairs.
- d) Maintaining regular contact with key customers.

2.8 Works Supervisor

The Works Supervisor is responsible for the production and repair of products passing through the workshop. He/ she is also responsible for the control of all personnel under his control and the control of the working environment and resources.

2.9 General Personnel

All personnel not listed above are responsible for performing the tasks allocated to them, and for complying with the specific procedures for their job functions. They are also responsible for the general upkeep and tidiness of their tools and working areas.