VIAMED LIMITED

MANAGEMENT SYSTEM DESCRIPTION

I.S.O. 9001 / 2015
I.S.O. 13485 / 2016
MDD / 93 / 42 EEC
CMDCAS

SYSTEM REQUIREMENT SPECIFICATION

PURPOSE

Viamed Ltd. Is totally committed to achieving the highest levels of Quality in all the products we supply and the services we provide. Our customers judge us by our products and services, therefore to succeed we enjoin our employees in sharing this objective and be totally committed in the outlook with regards to Quality.
One of the company's main objectives is to be able to continually meet the requirements of the various international standards, regulatory and statutory requirements to which we must conform and to which we have been assessed and approved. Continual conformance to the processes and systems within the company enables us to meet that objective.
The company also aims to utilise all relevant processes such as data analysis, decision-making, responsibilities, and resource development to improve its market position.
In addition to adherence to these processes, the company is continually developing and improving the right attitude towards quality achievement throughout. In this way we will continue to reach complete customer satisfaction.

SCOPE

This document describes the requirements of the company's management system, which is structured, to perform in accordance to the following standards and regulations:
ISO 9001:2015
EN 460001
ISO 13485:2016
MDD 93/42 EEC
CMDCAS.
The document acts as a reference to how the system is implemented, maintained and continually improved.
The product range and services provided by the company are:
The Design, manufacture, warehousing and distribution of Medical electronic equipment and accessories to hospitals, and the service and maintenance of such equipment.
Technical documentation, files and specifications for the above products and services are maintained and continually reviewed for completeness.

THE SYSTEM & ITS OBJECTIVES

The main objectives of Viamed Ltd are dependant upon the relationships with individual customers. As such they are deemed to be "dynamic", and therefore are subject to constant change. The core of the objectives, however, remains static throughout the company's operating system. These objectives form the basis for all processes used in the system, and are reflected in the various sub-processes.

The system operating within Viamed Ltd is not constrained by other influences and as such has freedom to be innovative. It is integrated into the basic structure of the

Company. The system is the key to achieving all the company's goals and objectives, it is designed so as to allow the company to anticipate performance trends and events and identify potential risks. Above all the system is designed to give the customers confidence that their needs and expectations will be met. A system model has been designed as can be seen in Appendix 1.

RESPONSIBILITIES

The responsibility for the direct management of the policies, objectives and strategies of the company is vested in the Board of Directors who, together with other management personnel, continually reviews the system and its top-level processes.
The authority for the implementation and maintenance of the system and its processes is vested in the Quality Engineer who is the management representative for these activities.
All personnel functions in the company, up to and including senior management, together with the associated reporting and communication channels, are described on the Organisation chart (Appendix 2) and Function Matrix (Appendix 3).
Process development teams are in place, which own and oversee the relevant processes. Analyses and conformance of which are regularly conveyed to the relevant process owner(s).
Each process owner is responsible for the arrangement of their individual team monitoring and its relative periodicity.

PROCESS CONTROLS

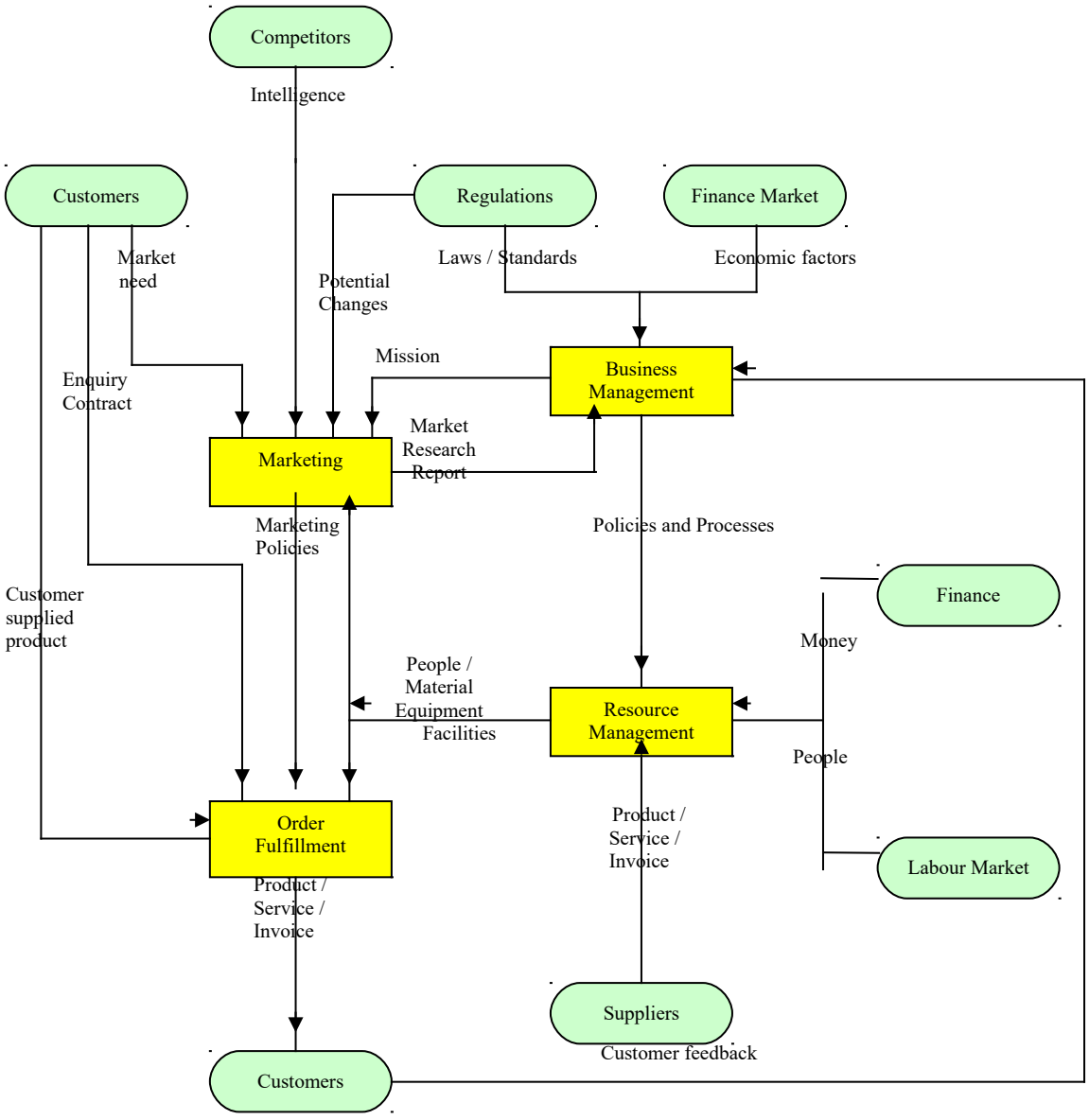
There are eight major processes within the company and these processes are defined as below:

a) Management System and documentation
b) Resource Management
c) Customer Requirements and satisfaction
d) Design and Development
e) Product Realisation
f) General Process control
g) Measurement Analysis and improvement
h) Corrective and Preventive actions

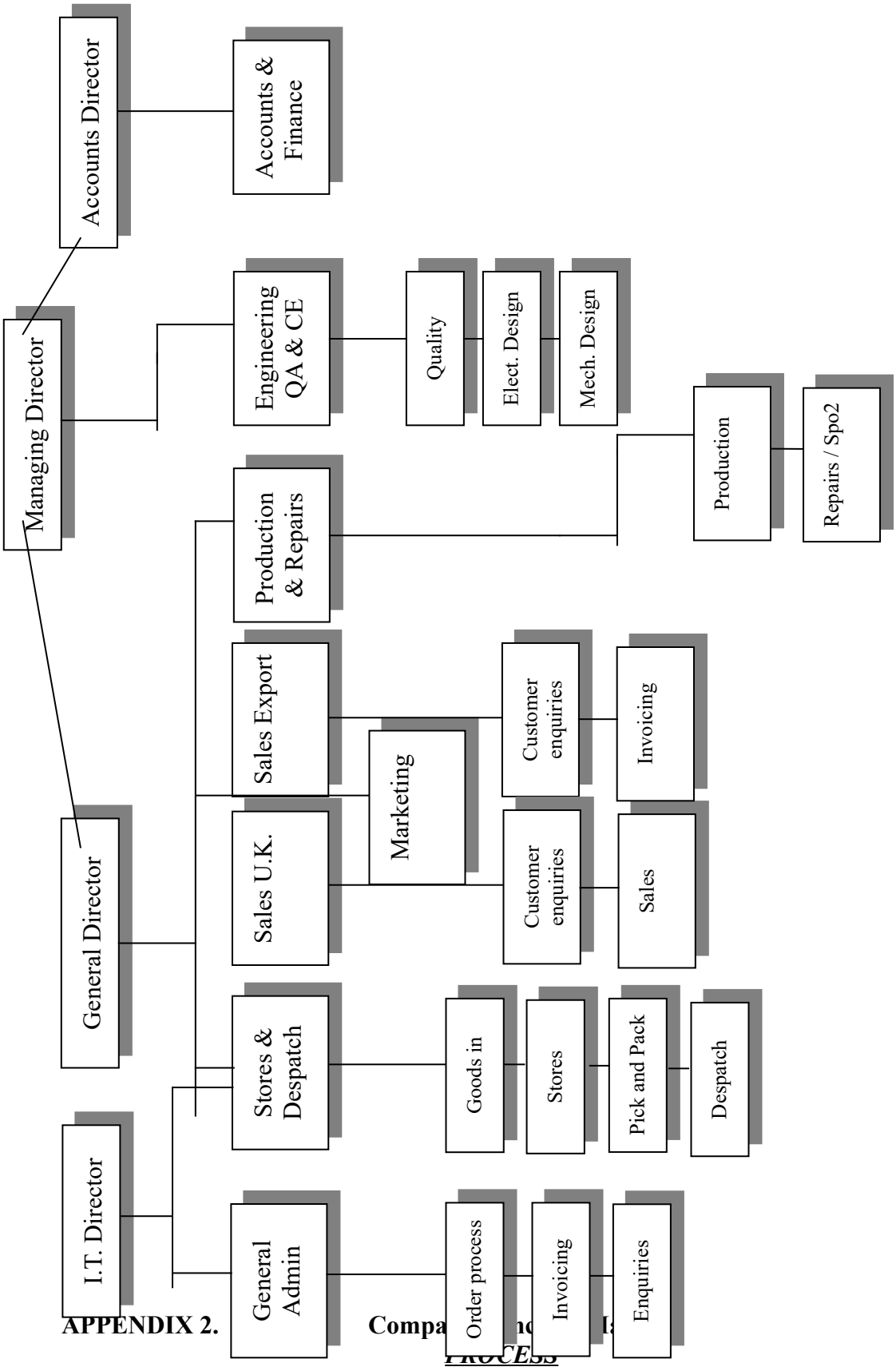
These major processes are also subdivided into their constituent parts as required by the company's business management system and its associated controls. Each process and sub-process is controlled by relevant flow diagrams as shown in Appendix 4. Where appropriate, processes will also be covered by associated operating procedures. Where one process interacts with another process in the system, then each process owner will contribute his or her respective inputs and outputs to the other's data analyses.*
The 8 major processes are monitored by the regular * meetings and the resultant records. The individual sub-processes are monitored by the internal audit system.
*

APPENDIX 1.

SYSTEM MODEL



APPENDIX 2. **Organisation Chart**



APPENDIX 2. **Compa[illegible]**

PROCESS

H

FUNCTION	A Management system	B Resource Management	C Customer Requirements	D Design & Development	E Product Realisation	F General Process Control	G Analysis & Data	Correction & Prevention
Board of Directors								
U.K. Sales								
Export Sales								
Quality Assurance								
Design								
Production								
Stock-Control								
Goods Inwards								
Accounts								

Appendix 4		**CHART No**
Process a)	**Management System and documentation**	**01**
Sub-process a1)	Management System	09
Sub-process a2)	Documentation	10
Process b)	**Resource Management**	**02**
Sub-process b1)	Provision of Resources	11
Sub-process b2)	Infrastructure & environment	12
Process c)	**Customer Requirements & Satisfaction**	**03**
Sub-process c1)	Sales	13
Sub-process c3)	Purchasing	15
Process d)	**Design & Development**	**04**
Sub-process d1)	Repairs and Manufacture	17
Sub-process d2)	Calibration	18
Process e)	**Product Realisation**	**05**
Sub-process c1)	*Sales*	*13*
Process f)	**General Process Control**	**06**
Sub-process f1)	Production	20
Sub-process f2)	Repairs	21
Sub-process f3)	Stock Control	22
Sub-process f4)	Packing & Despatch	23
Process g)	**Measurement, Analysis and Improvement**	**07**
Sub-Process g1)	Internal Audits	16
Sub-process g2)	Goods Inwards	24
Sub-process g3)	Process Inspection & Test	25
Sub-process g4)	Data Analysis	26
Process h)	**Corrective & Preventive Actions**	**08**
Sub-process h1)	Customer Complaints	27
Sub-process h2)	Quarantine & Hold Areas	28
Sub-process g3)	*Data Analysis*	*26*