VOP
Operating sub Process
<u>**Risk, Risk Management and Risk Analysis**</u>

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SCOPE

This procedure is established to describe the system used within the company for the control of Risk, Risk Management and Risk Analysis. It is used in conjunction with the individual sub procedures, which show the relevant information necessary. The purpose of this document is to bring together all the areas we have that define, monitor, analyse and report Risk, Risk Management and Risk Analysis.

RESPONSIBILITIES

It is the responsibility of the Managing Director, to ensure that the contents of this procedure, and related procedures and processes, are adhered to. He has the ultimate responsibility for directing and co-ordinating, all company Risk Management, and therefore ensuring that appropriate systems and procedures are in operation for, the success of the Quality Assurance Programme, through effective Risk management and Risk Analysis.

OBJECTIVES

It is the Objective of this VOP to demonstrate the processes involved, in the companies, in relation to Risk, Risk Management and Risk Analysis.
How we assess the Risk, Risk Management and Risk Analysis for effectiveness and who has responsibility for what areas / roles and who is ultimately responsible.
This document will bring together all the areas in the systems that define and monitor Risk throughout the companies.

Also refer to VM3COP18 Post Market Surveillance and VM3COP24.00 Overall Risk Analysis Program

AREAS OF RISK AND RESPONSIBILITIES

ISO Controller

The ISO Controller is responsible to the Managing Director. He is responsible for the Risk Management and Risk Analysis relating to ISO Standards, Supplier Review, Non Conformance Issues, Feedback, Resources Required and specifying Objectives. Has overall responsibility for Assessing Risk in Customer Complaints, Feedback and QA monitoring.

Accounts Controller

The Accounts Controller is responsible to the Managing Director for the Risk Management and Risk Analysis relating to all financial matters. Including debtors, creditors, wages, banking and VAT. Customs Activities. Also overall responsibility for processing customer sales and quotations.

<u>Directors</u>

Each director is responsible to the Managing Director and is responsible for Risk Management and Risk Analysis relating to directing and co-coordinating the day-to-day operations of the business. They are also responsible for the sales and purchasing functions and responsible for reporting any changes to risks or effectiveness to the Managing Director in relation to the above, or in any other areas they feel need to be reviewed.

<u>IT Controller</u>

The IT Controller is responsible for the Risk Management and Risk Analysis relating to the company's software and hardware and also responsible for Risk Management involved in purchasing functions, website technical maintenance, internal telephone and internet provision, off site backup of company data, software validation of internal QMS processes and Cyber Security. The IT Controller is also responsible for reporting any changes to risks to the Managing Director in relation to any of the above responsibilities.

<u>Health And Safety Controller</u>

The Health And Safety Controller is responsible for the Risk Management and Risk Analysis relating to the fire alarm and fire alarm maintenance, emergency lights and emergency lights maintenance, fire extinguisher and fire extinguisher maintenance, evacuation drill, first aider and monitoring First aider training, first aid boxes, accident book, review of the accident book and Risk Assessment HSE. The Health And Safety Controller is also responsible for reporting any changes to risks in relation to any of the above responsibilities, to the Managing Director.

<u>Maintenance Controller</u>

The Maintenance Controller is responsible for the Risk Management and Risk Analysis relating to the general maintenance of the buildings and infrastructure. The Maintenance Controller is also responsible for reporting any changes to risks to the Managing Director in relation to any of the above responsibilities.

<u>Human Resources Controller</u>

Human Resources Controller is responsible for the Risk Management and Risk Analysis relating to the employment of staff, processing CVs, interviewing, upholding employment law, maintaining staff, contracts, discipline, grievances, leave, training internal and external. Complying with GDPR, working environment and 7.1.4 Environment Of Operations. The Human Resources Controller is also responsible for reporting any changes to risks to the Managing Director, in relation to any of the above responsibilities.

<u>Office Team Leader</u>

The Office Team Leader is responsible for the Risk Management and Risk Analysis relating to day-to-day sales processing, sales order, office tasks, suppliers contact and other processes carried out

by the office. The Office Team Leader is also responsible for reporting any changes to risks to the Managing Director in relation to any of the above responsibilities.

Warehouse Team Leader
The Warehouse Team Leader is responsible for the Risk Management and Risk Analysis relating to the control of all dispatch processes affecting products and / or services. All incoming stock and day to day running of the warehouse. The writing of instrument check procedures and checklists, and maintaining up to date manufacturers or suppliers.
The Warehouse Team Leader also responsible for reporting any changes to risks to the Managing Director in relation to any of the above responsibilities.

QA and Technical Support Controller
The QA and Technical Support Controller is responsible for the Risk Management and Risk Analysis relating to Quality Assurance, repairs, maintaining up to date manufacturers or suppliers catalogues and technical data sheets, investigating customer complaints and warranty claims, the recall of suspect product procedure, maintaining the Calibration Index of test equipment. For the repairs and production of products passing through the workshop, QA functions with regards to the inspection of incoming products for stock and the function and safety testing of repaired items. Also technical investigation of non conforming products, quality assurance of incoming product and after repair, servicing of demonstration instruments and the quarantining of non conforming products.
The QA and Technical Support Controller is also responsible for reporting any changes to risks to the Managing Director, in relation to any of the above responsibilities.

Product Controller
The Product Controller is responsible for the Risk Management and Risk Analysis relating to price checking, product details and information, projects, product documentation requirements, manufacturing processes, yearly pricing review. Purchasing functions and controlling supplier documentation.
The Product Controller is also responsible for reporting any changes to risks to the Managing Director in relation to any of the above responsibilities.

Marketing Controller
The Marketing Controller is responsible for the Risk Management and Risk Analysis relating to mail shots, mailing lists, mailshot calendar, online web shop and web site.
The Marketing Controller is also responsible for reporting any changes to risks to the Managing Director in relation to any of the above responsibilities.

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Sales Controller
The Sales Controller is responsible for the Risk Management and Risk Analysis relating to visits to customers / potential customers, following up customer enquiries and quotations, customer complaints and minor repairs, sales responsibilities, customer pricing agreements and distributor agreements.
The Sales Controller is also responsible for reporting any changes to risks to the Managing Director in relation to any of the above responsibilities.

All personnel not listed above will be made aware regularly of Risk management obligation.

All of the Controllers are responsible to the Managing Director. For their areas, for assessing the risk in their areas and the effectiveness of their staff and associated risk in their areas.