

5.3 QUALITY POLICY

It is the policy of the organisation to provide a range of services, which meet the requirements of its customers and quality standard parameters, and that programmes are maintained on schedule at the agreed price. All work is carried out in a cost effective and timely manner, and in accordance with the highest professional standards aiming for continual improvement and customer satisfaction through the involvement and participation of all levels of management, staff and other interested parties.

A policy for quality conforming to the requirements of ISO13485, Medical Device Directive 93/42/EEC and Medical Device Regulation 2017/745 has been established to ensure that it:

- Is appropriate to the purpose of the organisation, the expected level of customer satisfaction and the needs of other interested parties
- Includes a commitment to meeting requirements and to continual improvement
- Has the resources needed and the contribution of suppliers and partners
- Provides a framework for establishing and reviewing quality objectives
- Demonstrates top management commitment and ensures the quality objectives are communicated, understood and implemented at appropriate levels of the organisation
- Is regularly reviewed at the management review meeting for suitability and effectiveness addressing continual improvement and client satisfaction.

Being a small but highly efficient and quality cost conscious organisation, and due to its size, a number of personnel have a dual role to carry out within its many aspects and functions. It is, however, organisation policy that this dual role shall not deter, in any manner, personnel from their prime objective of providing a quality service through an adequately controlled quality management system. The initial function of all management and employees shall be the maintenance of this objective.

Management is ultimately responsible for making balanced judgements, assessing the significance of variations in this sphere and taking decisions. In arriving at such decisions, the quality and personal integrity of staff are of fundamental importance. In this context, all effort is made to ensure that each person in the organisation understands that quality assurance is important to their future, know how they can assist in the achievement of adequate quality and are stimulated and encouraged to do so.

This policy is approved by the undersigned and is supported by all the levels of management within the organisation. All personnel shall be guided by the contents of the quality management system and no deviation from the methods and procedures set down shall be permitted.

Signed



Managing Director & Quality Manager

Date

20/12/24