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QUALITY POLICY NOTICE

The policy of the Company is to continuously improve its ability to provide products which consistently meet the customer requirements for performance, safety and quality, i.e. fitness for the intended purpose.

The management is committed to the following action on Quality:

- 1 To introduce and maintain a formal system of Quality Assurance according to statutory regulatory requirements, working to the scope:

"Design management, manufacture and repair of blood pressure measuring instruments, pressure infusion cuffs, and associated components".

The products handled are long established and illustrated in company catalogues and their design is frozen. For this reason no design resources are employed but should a newly identified risk necessitate a design change, or a new product added to the range offered to customers, suitably competent external resources, using appropriate procedures, will be employed.
- 2 To identify and review of all processes required to meet customer's needs and expectations to ensure effective control and monitoring and establish their interaction. Investigate the degree of customer satisfaction achieved in the supply of products and services and seek ways to improve it.
- 3 To review the resources available to meet quality objectives and provide such additional resources as are needed.
- 4 To review performance to maintain continual improvement of quality of services to customer and of the quality management system. To do so, objectives will be set up and maintained, with measurable indices and targets, and the progress made reviewed regularly by analysing data to identify routes to improvement.
- 5 To communicate their commitment to meet customer needs and expectations, and regulatory requirements. To also communicate with staff to ensure they are fully conversant with the procedures and methods introduced to enable them to participate in meeting objectives.

The Quality Manual sets out the general quality policies, procedures and practices making reference to supporting documents which provide greater detail, to ensure that the above policy is achieved in the most cost effective way. The scope of this quality system is ISO13485:2016, and the statutory regulatory requirements as defined in the Medical Device Directive 93/42/EEC.

All authorised holders of this manual shall ensure that this policy is understood, implemented and maintained at all levels in the organisation.

The policy and procedures for managing quality have been compiled in this manual so that they can be communicated effectively to all levels of personnel and implemented at all times. This manual and the procedures associated with it is authorised by me and issued on my behalf.

Signature

Hugh Templeton

Name: H. Templeton
Position: Quality Manager
Date: 20 January 2020
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