

Quality Policy

Platts & Nisbett Ltd operates a Quality Management System which has been designed in order to meet the requirements of the following:

ISO 13485:2016+A11:2021

Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

93/42/EEC

Medical Device Directive

(EU) 2017/745

Medical Device Regulation

21 CFR Part 820

Food and Drugs- Quality System Regulation

The Company is committed to complying with the requirements and maintaining the effectiveness and improvement of the Quality Management System, and the ongoing training and development of our staff.

Management shall:

- Ensure the quality policy and quality objectives are established for the QMS and are compatible with the context and strategic direction of the Company.
- The quality objectives shall be set and reviewed annually during the management review process and communicated to staff for regulatory awareness and to enhance customer satisfaction.
- Ensure that the resources needed for the QMS are available; including training, support and encouragement.
- Engage, and support persons who contribute to the effectiveness of the QMS.
- Maintain partnerships with suppliers and interested parties to provide an improved service.

Employees and other organisations are expected to co-operate and assist in the implementation of this policy, whilst ensuring that their own work, so far as is reasonably practicable, is carried out without risk to themselves, others, or the environment. This policy will be reviewed annually by management and where deemed necessary will be amended and re-issued.

This policy is endorsed by:-

A handwritten signature in purple ink, appearing to read 'A. Nisbett', is written over a horizontal line.

Signature

11/12/2023

Date

Company Director

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