



Quality Policy

(Version 7)

It is the policy of ProSys International Ltd to provide a range of services, which meet the requirements of its customers and quality standards and that customer programmes are maintained on schedule at the agreed price. All work is carried out in a cost effective manner and fulfilled on time, and in accordance with the highest professional standards aiming for continual improvement and customer satisfaction throughout the company. Its scope of activity includes:

ISO 13485:2016 MDSAP - design and manufacture of wound dressings for general medicine; manufacture of non-invasive bags, and catheters for urology, ostomy pouches, devices for stoma care and faecal management systems for general medicine.

This quality policy conforms with the requirements of the Medical Devices Standard - Quality Management Systems requirements for regulatory purposes EN ISO 13485:2016 MDSAP; the European Medical Device Directive 93/42/EEC (as amended); the USA Federal Food, Drug and Cosmetics Act (as amended); the KSA Medical Device Interim Regulation; the Canadian Medical Devices Regulations SOR/98-282, and the Australian Medical Devices Regulations AMDR:2002 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 maintaining the effectiveness of the quality management system
- Has the resources needed and the contribution of suppliers and partners
- Provides a framework for establishing and reviewing quality objectives
- Demonstrates top management commitment to Quality Assurance
- Is regularly reviewed at the management review meeting for suitability and effectiveness addressing continual improvement and client satisfaction.

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 of our decisions, are of fundamental importance. In this context, all effort is made to ensure that each person in the supply chain, understands that quality assurance is important to their future, know how they can assist in the achievement of top class quality and are stimulated and encouraged to do so.

This policy is approved by the undersigned and it is based on the premise that not only does ProSys International Ltd surpass Customer requirements, but it also complies with the relevant statutory & regulations requirements, in the country it operates.

A handwritten signature in black ink, appearing to read "Graham E Steer", written over a horizontal line.

Signed

Graham E Steer

6th March 2018