



ISO 13485:2016 Quality Policy Statement 2021-2022

Incus Surgical Ltd aims to be *'The Vital Link'* between Organisations in the field of Surgical Instruments and related industries. We have established this Quality Policy to be consistent with our Strategic Direction and the purpose and context of our organisation.

The Scope of our business is Manufacture, Supply, Inspection, Service & Repair of Non-Sterile, Non-Measurable Surgical Instruments, Internationally.

Incus Surgical Ltd operates simple, systemised, and transparent QMS processes. They drive accountability, productivity and external focus which provides a framework for the setting and reviewing of Quality Objectives at our Management Review Meetings, and for meeting our regulatory and legislative requirements and directives. The strategic direction of our Quality Policy comprises:

Customer focus: Customers are the heart of our business. We are committed to providing continuous service during these unprecedented times, and to continually review our processes, products, communication, and services to meet and exceed our customers' expectations.

Leadership: Top Management is committed to providing a working environment in which personnel can be assured that their mental well-being and physical health is at the forefront of ensuring we all work in a Covid-19 secure business. A Covid-19 policy has been issued to address these unforeseen issues.

Engagement of people: As an organisation, we recognise that people are the essence of any good business and that their full involvement enables their abilities to be used for our benefit. The team's full support, to enable provision of continuous service to our key clients throughout the past year, is testament to everyone's commitment.

Process approach: We have established Quality Systems and monitor processes against performance targets set within business plans, SLA's, KPI's and Quality Objectives which are reviewed, at the very least, annually.

Improvement: We are committed to achieving continual improvement across all aspects of our Quality Management System, business, and infrastructure - the basis of our annual objectives and strategic direction.

Evidence-based decision making: We are committed to only make decisions relating to our QMS following an analysis of relevant data and information to maintain its effectiveness.

Relationship management: **Incus Surgical Ltd** recognises that an organisation and the relationship it has with its external providers are interdependent, and a mutually beneficial relationship enhances the ability to create value and provide continuous supply and service.

Incus Surgical Ltd is committed to Quality Excellence and to meeting the requirements of other interested parties, meeting our regulatory, social, environmental, health and well-being and charitable responsibilities.

We have produced quality objectives which relate to this policy and they can be found in document **QMF5.02** Quality Objectives.

This policy is available/communicated to all interested parties as well as being made available to the wider community through publication on our Company Noticeboard and on our Website.

www.incus-surgical.com

Authorised by: Peter Rae, Managing Director

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Date	Version	Change Doc.	Title	Authorised by:	Page No.
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