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QUALITY POLICY

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1. PURPOSE

The purpose of this procedure is to establish and maintain a consistent and effective method of this document is to establish and communicate the company's Quality Policy to ensure that the organization meets all regulatory, customer and quality objectives in relation to the company's products and services.

While this is a stand-alone procedure it should be read in conjunction with the company's Quality Manual and other related SOP's and normative references provided below. This SOP facilitates alignment between different parts of the organization, including SOPs outside the scope of the ISO13485:2016 Quality Standard. These include environmental management, occupational health and safety management, financial management and human resources management.

Implicit in this SOP is the expectation that all employees of the company, with management, will strive to continuously improve its systems and procedures; ensure that all are competent, motivated, and committed to continuous improvement.

2. SCOPE

Requirements of this SOP are applicable to all employees, management, and directors of the company, as well as third party sales intermediaries and others working on behalf of iSpine.

3. RESPONSIBILITIES

Detailed responsibilities are allocated in the workflow procedure and are divided into:

- Accountable – The management member who is responsible for the execution of the procedure/sub-procedure. The accountable person is also the process owner.
- Responsible – The person who executes the procedure or a part thereof.
- Consulted – any internal or external person who must be consulted. This indicates bilateral communication and may result in an approval, as the case may be.
- Informed – any internal or external person who must be informed of the progress or result of a process/procedure.

The SOP owner is the Managing Director who is responsible to ensure that this procedure is reviewed every two years, that amendments are properly done, and that training is provided to all employees responsible for any part of this SOP.

Refer to the Responsibility Matrix, which provides a detailed list of personnel responsibilities in relation to the Quality Management System.

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4. QUALITY POLICY STATEMENT

With a combined 85 years' experience in spinal surgery, we source the best in class spinal orthopedic and neurosurgical products. These products offer surgeons a comprehensive range of options and solutions for their patients.

Our products meet the exact standards of the Regulatory Authorities and the expectations of our customers.

We have implemented a Quality Management System to ensure consistent conformity of products and services with regulatory and customer requirements.

Product innovation and assessment is an ongoing process to ensure we and our customers remain on the cutting edge of appropriate technologies for the South African Healthcare Market.

5. RELATED DOCUMENTS

Reference	Title	Note
H-PR-001_04	Responsibility Matrix	A comprehensive list of personnel allocating responsibilities for various tasks under the Quality Management System. This is also linked to training and competency requirements for personnel responsible for implementation of the Quality Management System
Q-PR-006	Quality Plan	The quality plan is held on Monday.com and can be accessed using the following link. https://view.monday.com/5499504070-ba8ed8355075bcad45b81fc5375139bc?r=use1

6. NORMATIVE REFERENCES

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- Quality Manual
- Site Master File
- ISO 13485:2016
- SANS 1541 – Hospital Loan Sets
- The Medicines and Related Substances Act 101 of 1965 as amended.
- Regulations relating to Medical Devices and *in vitro* Diagnostic Medical Devices (IVDs) published in terms of Section 35 of the Medicines and Related Substances Act 101 of 1965.

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7. TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given below shall carry specific meaning:

- SOP – Standard Operating Practice, also referred to as a Policy or Procedure.
- Policy – A statement of intent.
- Procedure (Process), a sequence of activities which shall have required inputs and outputs.
- Inputs – information or documents required to perform the procedure.
- Outputs – of a SOP are Control Records.
- Process – see *Procedure*.
- Control Records – All records required by this SOP which prove that the process has been followed and required for verification or validation.

8. APPROVALS

	eSignatures
Drafted by Mark Banfield & Associates Consulting	
Reviewed by Belinda Malan Management Representative	 Belinda Malan (Nov 27, 2023 15:41 GMT+2)
Approved by Wayne Roach Managing Director	 Wayne Roach (Dec 4, 2023 21:56 GMT+2)

9. REVISION HISTORY

Date	Reason for Update	Version
June 2017	Original	1.0
31 August 2019	Upgrade to 2016 version of the standard, alignment with Guideline on Medical Device Quality Management System and general process improvements.	2.0
16 November 2020	Insertions: Responsibility Matrix eSignatures Block Table of Contents Figures Update: Normative References	2.1
13 November 2023	Spelling and grammar checked. Management Representative changed.	3.0

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	Letterhead updated. Formatting corrections done. Correct version from 2.1 to version 3 Corrected normative references	
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Note: Number indicates material change, and decimal indicates administrative or drafting (Minor) change.

Q-PR-002 - iSpine Quality Policy V3

Final Audit Report

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