POPIA Compliance Document for Jehu Industries

This document outlines Jehu Industries' commitment to complying with the Protection of Personal Information Act (POPIA) of South Africa, while also adhering to the requirements of ISO 13485:2016 for Medical Devices Quality Management Systems and the South African Health Products Regulatory Authority (SAHPRA) guidelines.

1. Introduction to POPIA

The Protection of Personal Information Act (POPIA) aims to protect the personal information of individuals and requires responsible parties to process personal information lawfully and reasonably. Jehu Industries acknowledges its responsibilities as a responsible party under POPIA.

2. Scope and Application

This policy applies to all personal information processed by Jehu Industries, including but not limited to information pertaining to employees, customers, suppliers, and other stakeholders, within the context of our medical device operations.

3. Principles of POPIA and their Application in Jehu Industries

Jehu Industries is committed to upholding the eight conditions for the lawful processing of personal information as stipulated by POPIA:

3.1. Accountability

Jehu Industries takes full responsibility for personal information in its possession or under its control. A designated Information Officer has been appointed to ensure compliance with POPIA.

3.2. Processing Limitation

Personal information will be processed lawfully and in a reasonable manner that does not infringe on the privacy of the data subject. Processing will be kept to a minimum, relevant, and not excessive for the purpose.

3.3. Purpose Specification

Personal information will be collected for specific, explicitly defined, and lawful purposes related to Jehu Industries' medical device manufacturing and distribution activities, as required by ISO 13485:2016 and SAHPRA regulations. Data subjects will be made aware of the purpose of collection.

3.4. Further Processing Limitation

Further processing of personal information will be compatible with the purpose for which it was initially collected, unless a legal obligation or explicit consent dictates otherwise.

3.5. Information Quality

Jehu Industries will take reasonable steps to ensure that personal information collected and processed is complete, accurate, not misleading, and updated where necessary.

3.6. Openness

Jehu Industries will maintain openness about its personal information processing activities. Data subjects will be informed about the information being collected, the source (if not from them), the purpose of collection, and their rights.

3.7. Security Safeguards

Appropriate, reasonable technical and organizational measures will be implemented to prevent loss of, damage to, or unauthorized access to or destruction of personal information. This aligns with the risk management requirements of ISO 13485:2016.

3.8. Data Subject Participation

Data subjects have the right to access their personal information held by Jehu Industries and to request correction, destruction, or deletion of their information.

4. Integration with ISO 13485:2016 Quality Management System

Jehu Industries' POPIA compliance measures are integrated into its ISO 13485:2016 certified Quality Management System (QMS).

- **Documentation Control (Clause 4.2.3):** All policies, procedures, and records related to personal information processing are controlled within the QMS.
- **Management Responsibility (Clause 5):** Management is committed to ensuring the effective implementation and maintenance of this POPIA policy, as part of the overall QMS.
- **Resource Management (Clause 6):** Adequate resources, including personnel training, are allocated to ensure POPIA compliance.
- **Product Realization (Clause 7):** Personal information collected during product realization (e.g., customer feedback, clinical data) will adhere to POPIA principles.
- **Measurement, Analysis, and Improvement (Clause 8):** The effectiveness of POPIA compliance will be monitored, reviewed, and continually improved upon, aligning with the QMS's continuous improvement cycle.

5. Compliance with SAHPRA Regulations

As a medical device manufacturer, Jehu Industries recognizes its obligations under SAHPRA regulations, which often involve the processing of sensitive personal information related to health.

- **Clinical Data:** Personal health information collected during clinical investigations or post-market surveillance will be processed with the utmost care, ensuring strict adherence to POPIA's conditions for sensitive personal information and SAHPRA's data protection guidelines.
- **Adverse Event Reporting:** While SAHPRA requires reporting of adverse events, Jehu Industries will ensure that personal information included in

such reports is minimized and appropriately anonymized or de-identified where possible, in accordance with POPIA.

- **Product Traceability:** Where personal information is linked to product traceability, robust security measures will be in place to protect such data, balancing SAHPRA's traceability requirements with POPIA's privacy principles.

6. Data Breach Management

Jehu Industries has established procedures for identifying, managing, and reporting data breaches involving personal information, in line with POPIA's notification requirements and the incident reporting procedures within the ISO 13485:2016 QMS.

7. Training and Awareness

All Jehu Industries personnel who handle personal information will receive appropriate training on POPIA, ISO 13485:2016, and SAHPRA data handling requirements.

8. Review and Update

This POPIA Compliance Document will be reviewed and updated periodically to ensure its continued relevance and effectiveness, taking into account any changes in legislation, regulatory requirements, or organizational practices.