

PAIA Manual for Jehu Industries

Introduction to PAIA

The Promotion of Access to Information Act (PAIA) No. 2 of 2000 was enacted to give effect to the constitutional right of access to any information held by the state or by any other person that is required for the exercise or protection of any rights. Jehu Industries is committed to upholding the principles of transparency and accountability as enshrined in PAIA.

Company Information

Detail	Description
Company Name	Jehu Industries
Information Officer	Jeremy Naidoo
Contact Details	Jehu Industries Address: 11, Paramount Park, 75 Siphosethu Rd, Mount Edgecombe, Durban, 4300 Phone: 031 537 8054 Website: https://www.jehuindustries.com/contact-us/ Email: info@jehuindustries.com

SAHPRA and ISO 13485:2016

Jehu Industries operates within the medical device industry, which is regulated by the South African Health Products Regulatory Authority (SAHPRA). Our quality management system adheres to the standards set out in ISO 13485:2016, which specifies requirements for a comprehensive management system for the design and manufacture of medical devices.

Information Subject to SAHPRA Regulations

Information pertaining to product registrations, clinical trials, adverse event reporting, and quality system documentation submitted to or maintained in accordance with SAHPRA regulations may be accessible under PAIA, subject to the relevant exemptions.

Information Subject to ISO 13485:2016 Requirements

Our ISO 13485:2016 compliant quality management system generates various documents, including but not limited to:

- **Quality Manual:** Outlines the overall quality management system.
- **Procedures:** Detailed instructions for various processes.
- **Work Instructions:** Specific steps for tasks.
- **Records:** Evidence of activities performed (e.g., design history files, production records, complaint files).
- **Management Review Minutes:** Records of periodic reviews of the quality management system.

Access to these documents will be managed in accordance with PAIA, taking into consideration confidentiality, intellectual property, and other legitimate interests.

How to Request Information

Requests for information held by Juhu Industries must be made in writing to the Information Officer. The request form prescribed by the Minister of Justice and Constitutional Development must be used. The form is available on the website of the Department of Justice and Constitutional Development.

The request must specify:

- Sufficient detail to enable the Information Officer to identify the record and the requester.
- The form of access required (e.g., a copy of the record or an opportunity to inspect the record).
- If the record is required for the exercise or protection of a right, an explanation of the right to be exercised or protected and why the record is required for the exercise or protection of that right.

- The postal address or fax number of the requester within the Republic, or if the requester wishes to be informed of the decision in any other manner, the manner and particulars of that manner.
- If the request is made on behalf of another person, proof of the capacity in which the requester is making the request to the reasonable satisfaction of the Information Officer.

Fees

A request for access to information may be subject to prescribed fees. The fee structure is available from the Information Officer upon request.

Remedies Available to a Requester

If a request for access to information is refused, the requester may lodge an internal appeal against the decision or apply to a court for appropriate relief.

Availability of the Manual

This manual is available at the offices of Jehu Industries during normal business hours and on our official website.