

# Disclaimer

This disclaimer document outlines important limitations and conditions regarding the products and services provided by Jehu Industries. It is intended to ensure compliance with relevant regulatory standards, including ISO 13485:2016 and requirements set forth by the South African Health Products Regulatory Authority (SAHPRA).

## 1. Scope of Products and Services

Jehu Industries specializes in the manufacturing and supply of medical devices. Our products are designed and produced in accordance with strict quality management system requirements to meet their intended purpose.

## 2. Intended Use

All medical devices supplied by Jehu Industries are for professional use by qualified healthcare practitioners and trained personnel only. It is the responsibility of the user to ensure that they have the necessary qualifications, training, and experience to safely and effectively use our products. Any use of our products outside of their intended use, as specified in the product labeling and instructions for use, is strictly prohibited and will void all warranties and liabilities.

## 3. Compliance with ISO 13485:2016

Jehu Industries operates a Quality Management System (QMS) that is certified to ISO 13485:2016. This certification demonstrates our commitment to meeting regulatory requirements and ensuring the safety and performance of our medical devices. While we adhere to the principles of ISO 13485:2016, this certification does not imply that our products are free from all possible risks or errors. Users are still responsible for exercising due diligence in their application and use.

## 4. Compliance with SAHPRA Regulations

Our medical devices are registered with and approved by the South African Health Products Regulatory Authority (SAHPRA) where required. Jehu Industries endeavors to comply with all applicable SAHPRA regulations concerning the

manufacturing, labeling, distribution, and post-market surveillance of medical devices in South Africa. Users should be aware of and comply with all local regulations and guidelines governing the use of medical devices in their respective jurisdictions.

## **5. Limitations of Liability**

Jehu Industries shall not be liable for any direct, indirect, incidental, special, or consequential damages arising from the misuse, improper application, unauthorized modification, or negligence in the use of our products. This includes, but is not limited to, damages for loss of profits, business interruption, or loss of data. Our liability is limited to the replacement or repair of defective products as per our warranty policy.

## **6. Product Information and Instructions for Use**

It is the responsibility of the user to thoroughly read and understand all product information, including labels, packaging inserts, and instructions for use (IFU) provided with our medical devices. These documents contain critical information regarding the safe and effective use, contraindications, warnings, and precautions associated with each product.

## **7. Reporting Adverse Events**

In accordance with ISO 13485:2016 and SAHPRA regulations, users are required to report any adverse events, product malfunctions, or quality concerns related to Jehu Industries' medical devices to us promptly. This enables us to investigate and take appropriate corrective and preventive actions.

## **8. Intellectual Property**

All intellectual property rights, including trademarks, copyrights, and patents, pertaining to Jehu Industries' products and documentation are owned by or licensed to Jehu Industries. Unauthorized reproduction, distribution, or modification of our products or documentation is strictly prohibited.

## 9. Revisions to Disclaimer

Jehu Industries reserves the right to revise or update this disclaimer document at any time without prior notice. The most current version will always be available on our official website or upon request.

## 10. Contact Information

For any questions or concerns regarding this disclaimer or our products, please contact Jehu Industries through the following channels:

- **Email:** [info@jehuindustries.com](mailto:info@jehuindustries.com)
- **Phone:** +27 11 123 4567
- **Website:** [www.jehuindustries.com](http://www.jehuindustries.com)

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