Kemenkes

Medical Device Regulation in Indonesia (Update)

Ministry of Health of the Republic of Indonesia

www.kemkes.go.id

OUTLINE

- OVERVIEW OF INDONESIA MEDICAL DEVICE REGULATION
- HALAL REGULATION FOR MEDICAL DEVICE
- THE PHARMACEUTICAL AND MEDICAL DEVICES DICTIONARY (KFA)
- QUICK WIN PROGRAM RELATING MEDICAL DEVICE

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Indonesian Medical Device Landscape at a Glance

15.931
Item Medical Devices (Local Product)

454
Type of Medical Devices (Local Product)

828
Medical Devices Manufacturers

Indonesia is divided into **38 provinces**.

57.541
Item Medical Devices (Import Product)

1.568
Type of Medical Devices (Import Product)

5.328
Medical Devices Distributors

Indonesia consist of **five main islands** and some 30 smaller archipelagoes, totaling about **18,110 islands and islets** with a population of around **270 thousand million people.**

As a medical equipment market, there are **34,800 health facilities** consisting of hospitals, public health centers, clinics and laboratories.

Souce:
Data of licensed product, product type, producer and distribution is per 1 October 2024 (regalkes.kemkes.go.id)
Number of medical device producers does not include those published through the Ministry of Industry
Number of health facilities from kemkes.go.id and perizinan-yankes.kemkes.go.id/fo/

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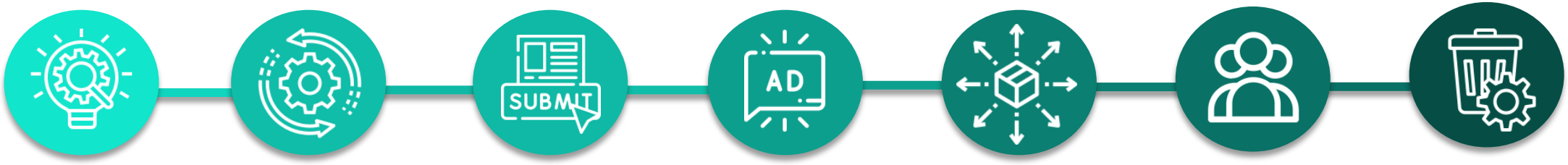
MEDICAL DEVICE LIFE CYCLE MANAGEMENT



Product Research & Development | Production | Registration / Product License | Advertisement | Distribution | Consumer | Disposal

Pre-Market Control

Manufacturer License
GMP
GDP
Distributor License
Product License

Post-Market Control

Sampling → Monitoring → Vigilance → Advertising → Enforcement & audit

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Quality Management System

Medical Devices Industry

- Mandatory implementation of GMP-MD Guidance, developed by MOH and adopted from ISO 13485:2016 ➔ Cara Pembuatan Alat Kesehatan yang Baik (CPAKB)
- MoH Regulation No. 20 of 2017 on GMP-MD Guidance
- MoH Regulation No. 14 of 2021

Medical Devices Distributor

- Mandatory implementation of GDP-MD Guidance ➔ Cara Distribusi Alat Kesehatan yang Baik (CDAKB)
- MoH Regulation No. 4 of 2014 on GDP-MD Guidance
- MoH Regulation No. 14 of 2021

The certification process is conducted by MoH

POST MARKET SURVEILLANCE

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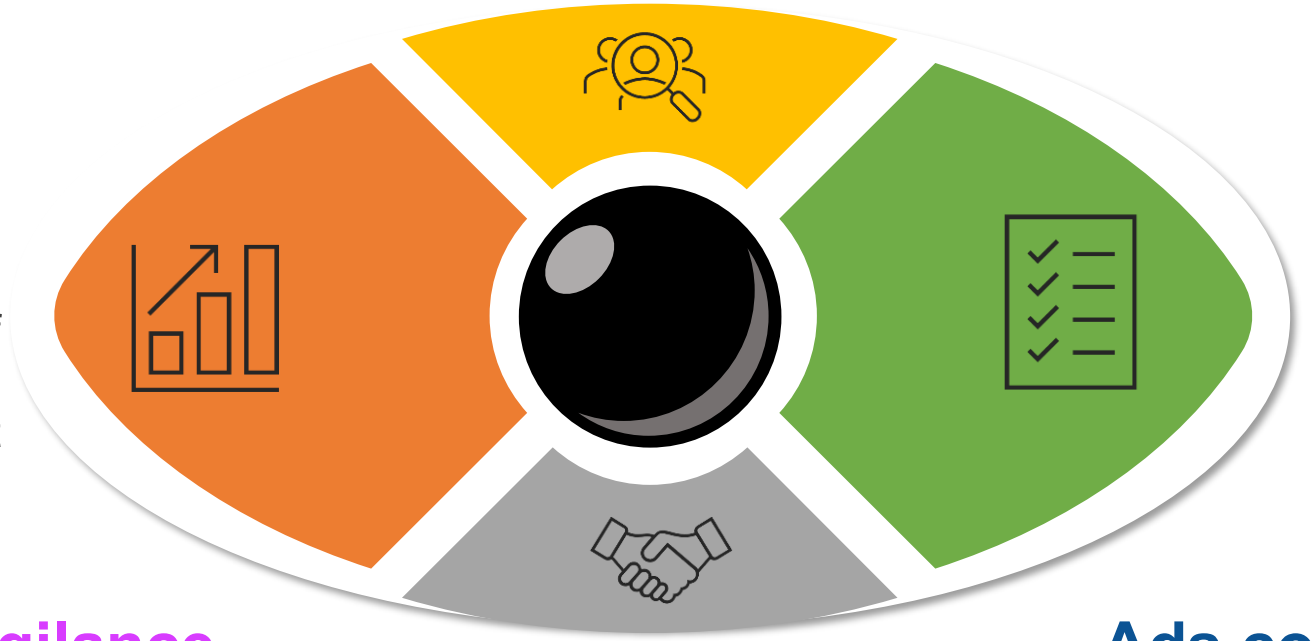
Product Inspections

Product mapping and inspections at licensed manufacturer/distributor

Sampling and Testing

To ensure the safety, quality and efficacy/performance of medical devices in the market



Labeling Surveillance

Must provide objective, complete, and not misleading information.

Vigilance

Identification, evaluation, comprehension, and prevention of adverse effects or other issues associated with the use of medical devices

Ads controlling

Mechanism controlling of medical device advertisement in all kinds of media, to ensure the conformity with the regulation.

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Halal Product Assurance for Medical Device

- All products **imported, distributed and traded in Indonesia** must be halal certified, including Medical Devices. (Article 4 of Law 33/2014)
- Products that shall be obliged to be halal certified are those **originating from and/or containing animal ingredients**. (Article 138 of GR 39/2021)
- Products originated **from non-Halal materials are excluded** from the obligation to be halal certified. (Article 27 of MORA 26/2019)
- Products made of **non-Halal materials** may be imported, distributed and traded within the territory of Indonesia. However, they must disclose this information through appropriate **labeling**. (Article 142 of MORA 26/2019 / Article 26 of Law 33/2014)
- Halal certificates issued by foreign halal institutions can be accepted as fulfillment of Halal Certification requirements based on mutual acceptance agreement of Halal Certificates. (Article 128 of MORA 26/2019)
- The obligation to be certified halal is being **implemented in stages**. (Article 139 of GR 39/2021)

Stages of the Obligation to be Halal Certified

	MORA 26/2019 & GR No 39/2021
Class A	17 October 2026
Class B	17 October 2029
Class C	17 October 2034
Class D	**Not yet determined**

Label for Non-halal Medical Device

The product contain non halal material

Bahan Tidak Halal

The material is halal, but the production process doesn't meet the halal requirement

Proses Belum Halal

We are currently increasing various efforts to increase the durability of medical equipment in ensuring that the medical equipment needed for health services is available.

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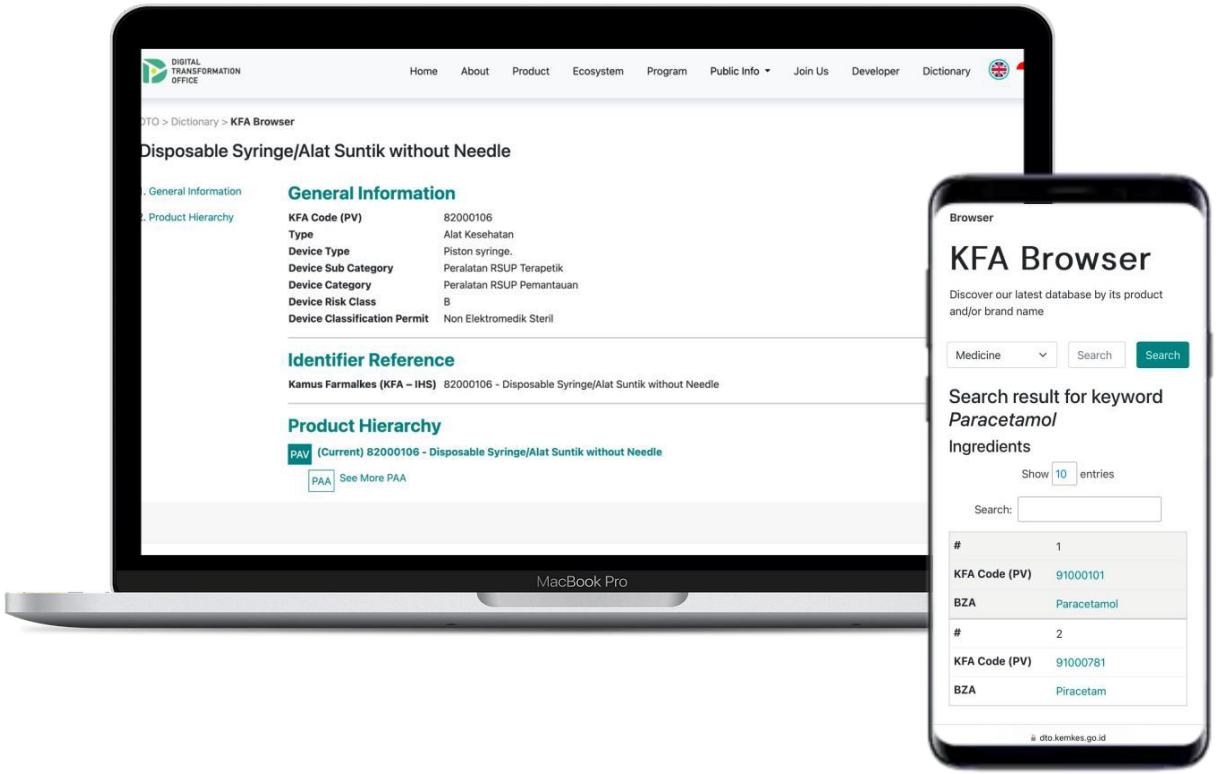
Kamus Farmasi dan Alat Kesehatan (KFA)

The Pharmaceutical and Medical Devices Dictionary



"The Pharmaceutical and Medical Devices Dictionary (KFA) is a dictionary that contains unique codes for pharmaceutical and medical device products so that it can be used and integrated into all systems used by health industry workers."

KFA BROWSER

satusehat.kemkes.go.id/kfa-browser/

API KFA

https://satusehat.kemkes.go.id/platform/docs/id/master-data/kfa/rest-api-kfa/

Web browser **can be accessed by the public**

Can display **a list of medical devices based on Medical Device Type**

Can display **a list of medical devices based on Medical Device Subtype**

Can display **a list of medical devices based on Template/ Shell Products**

Can display **a list of medical devices based on Variant Products**

MEDICAL DEVICE DISTRIBUTION BUSINESS PROCESS**

Business Workers

Regalkes*

Seralkes*

Marketing Authorization Number Owner (PIE)

SATUSEHAT

KFA*

Sectoral Catalog

User / Health District Hospital

Distributor

Non Marketing Authorization Number Owner (Non-PIE)

ASPAK*

SIKN*

SATUSEHAT

National Health Information System

National Inventory List

*Application System

**Distribution of Medical Devices is carried out in accordance with Good Distribution Practices (CDB)

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QUICK WIN PROGRAMME

"We are committed to providing free health check-ups, reducing TB cases by 50% within five years, and establishing high-quality, fully equipped hospitals in every district."

FREE HEALTH CHECK-UPS

Organized according to life cycle stages and conducted at Primary Healthcare Facilities.

ENHANCING TB CONTROL EFFORTS

- Detection of 1,035,500 cases.
- Treatment initiation for 95% of detected cases.
- Treatment success rates: 95% for Drug-Sensitive TB and 75% for Drug-Resistant TB.

HIGH-QUALITY COMPREHENSIVE HOSPITALS

66 locations are targeted to be equipped with facilities equivalent to Class C hospitals across districts/cities.

Medical devices that meet Quality, Safety and Efficacy requirements.

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Kementerian Kesehatan RI