KEMENTERIAN
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INDONESIA

OVERVIEW
INDONESIA MEDICAL DEVICES REGULATION

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MINISTRY OF HEALTH THE REPUBLIC OF INDONESIA
2022

Health System Transformation 2021-2024

5 National Mid-Term Development Plan (RPJMN) and 6 Pillars of Health System Transformation 2021-2024

Vision

In line with the President's vision to create healthy, productive, independent and just people

Outcome of the RPJMN in the health sector

- Improve the health of mothers, children, family planning and reproductive health
- Accelerate improvement of community nutrition
- Improve disease control
- Healthy Movement Culture (GERMAS)
- Strengthen the health system & drug and food control

6 main categories

1 Primary service transformation

a. Population education

7 main campaigns: immunization, balanced nutrition, exercise, anti-smoking, environmental sanitation & hygiene, disease screening, medication adherence

b. Primary prevention

Addition of routine immunization to 14 antigens and expansion of coverage throughout Indonesia

c. Secondary prevention

Screening for the 14 highest causes of death in each age target, screening for stunting, & increasing ANC for maternal & infant health

d. Increasing the capacity and capability of primary care

Puskesmas in 171 sub-districts, fullfillment of 40 essential medicines and primary health human resources

Secondary service transformation

Increasing access and quality of secondary & tertiary care

Hospitals in the Eastern Region, a network of 6 superior services, partnerships with the world's top healthcare centers

3 Health security system transformation

a. Increasing resilience of pharma & med devices sector

Domestic production of 14 routine vaccines, top 10 drugs, top 10 medical devices by volume & by value

b. Strengthening emergency response resilience

National network of lab-based surveillance, emergency response reserve personnel, table top exercise of crisis preparedness

4 Healthcare financing transformation

Health financing regulation with 3 objectives: available, sufficient, and sustainable; fair allocation; and effective and efficient utilization

5 Health workers transformation

Addition of student quotas, domestic & foreign scholarships, ease of equalizing health workers for overseas graduates

6 Health technology transformation

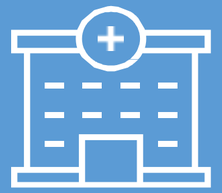
Development and utilization of technology, digitalization, and biotechnology in the health sector

This is the pivotal moment for Indonesia to reform health

There has never been a more opportune time for healthcare transformation

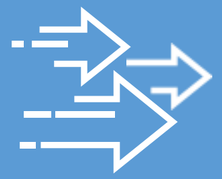
Covid-19 has made healthcare thenumber one priority

Population is more aware and realize the importance of healthcare; institutions and organizations also understand the importance of keeping their workforce healthy. The need for medical devices and products for handling COVID-19 has increased significantly



The pandemic surfaced the need to strengthen healthcare resiliency

Fighting the pandemic has uncovered systemic gaps that needs to be fixed to improve our health system capability and its Resilience. There is insufficient medical device for handling COVID-19



Indonesia healthcare system is ready for transformation

The right momentum for health transformation digital health technologies are more common place and the population is ready to embrace change

Legal Basis for Quality Assurance of Medical Devices

1. **Law No. 36 of 2009 on Health**
   Article 106 as amended in Law Number 11 of 2020 regarding **Job Creation Law Article 60 (Omnibus Law)**

2. **Government Regulation No . 5 / 2021**
   Implementation of Risk-Based Business Licensing

3. **Regulation MoH No. 14/2021**
   Standards for Business Activities and Products in the Implementation of Risk-Based Business Licensing in the Health Sector

4. **Regulation MoH No. 62/2017**
   Product License of Medical Devices, In Vitro Diagnostic Medical Devices and Household Health Products

Any Medical Devices, In Vitro Diagnostic Medical Devices and PKRT which are produced, imported, assembled and/or repackaged for distribution within the territory of the Republic of Indonesia **must have Product License (Registration number)**

INDONESIA PRE- AND POST-MARKET CONTROL OF MEDICAL DEVICES

Product Research and Development → Production → Registration/ product License → Adver tisme nt → Distribution → Consumer → Disposal

PRE MARKET ← → POST MARKET

Manufacturer

- Manufacturer License
- GMP Certificate (CPAKB)

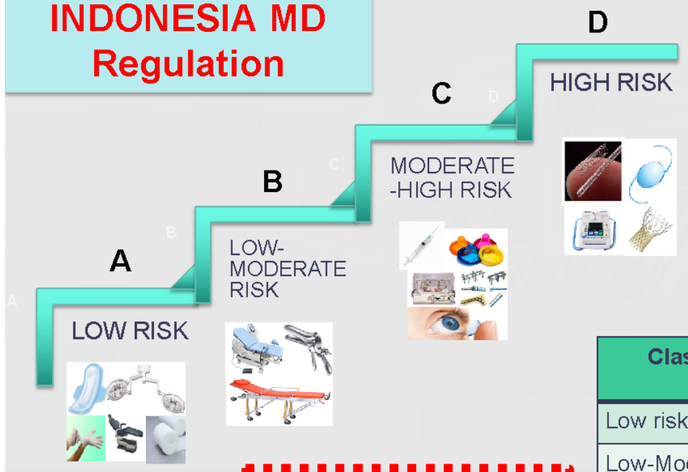
Product License

- Ensure the safety, quality and performance of MD

Distributor

- Distributor License
- GDP Certificate (CDAKB)

INDONESIA MD Regulation



Indonesia has ratified ASEAN Medical Device Directives in 2018

Classification	AMDD (ASEAN MED DEV DIRECTIVES)	EU
Low risk	A	I
Low-Moderate risk	B	IIa
Moderate-High risk	C	IIb
High risk	D	III

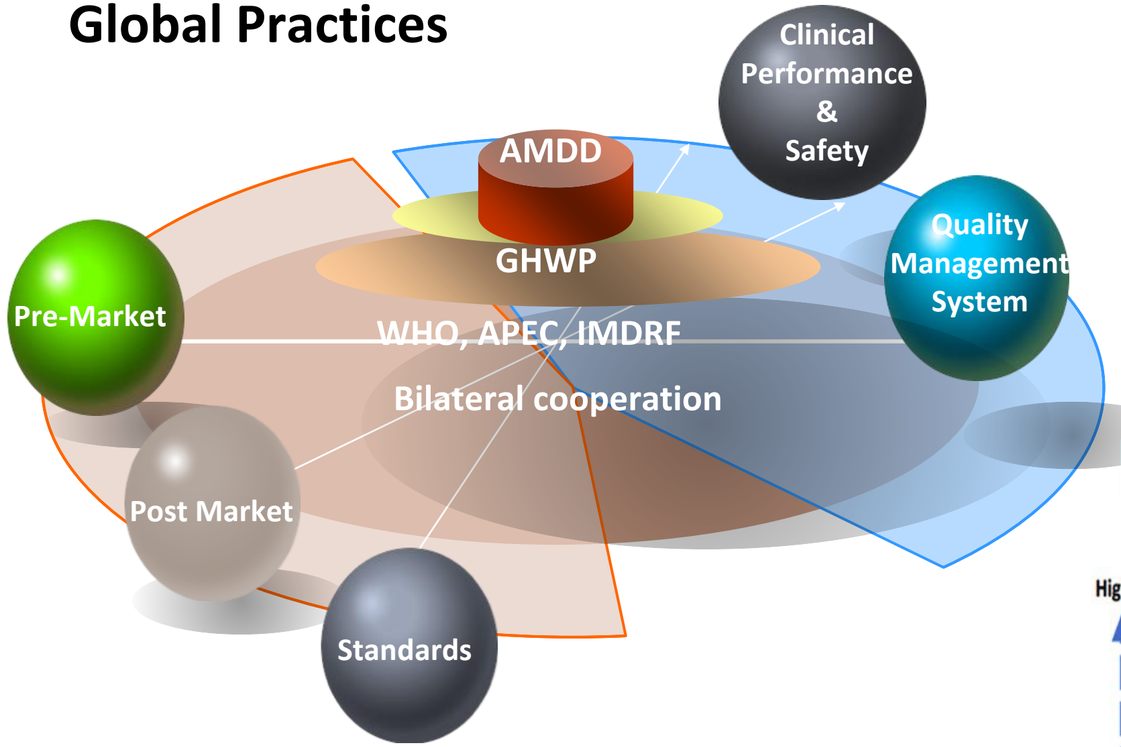
Risk Clasification is based on the potency of risk that caused

Post Market Control :

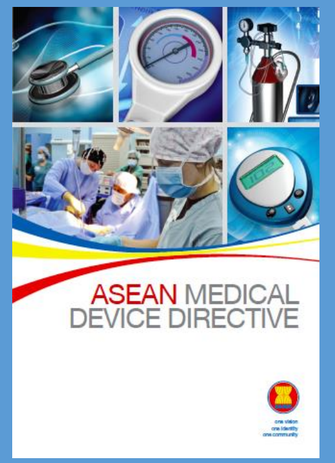
- Sampling and Testing
- Advertisements Control
- Inspection of Medical Device Facilities / Products and Household Health Products
- Post Border Monitoring
- Audit
- Vigilance

Regulation on Medical Device Sector

Indonesia Medical Device Regulation Based on Regional and Global Practices

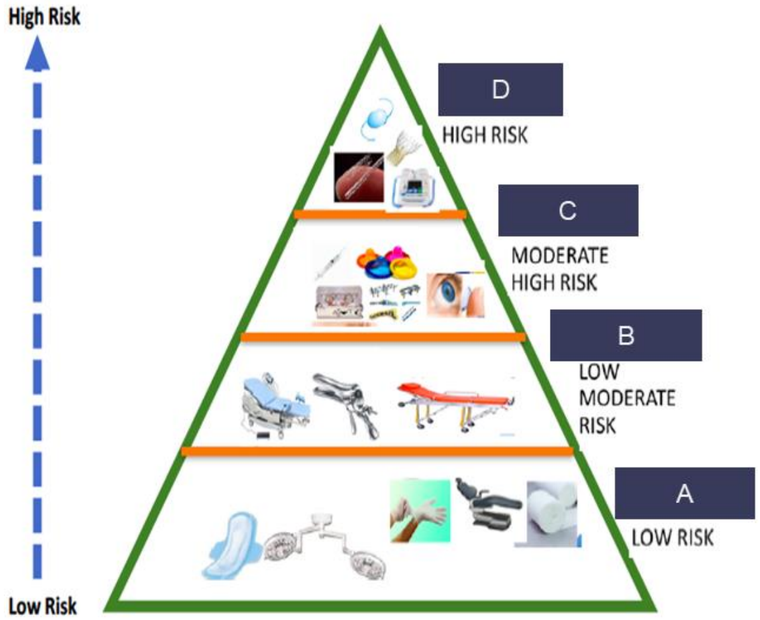


ASEAN Medical Device Committee (AMDC)
AMDC TC chair 2015-2021



RISK CLASSIFICATION → **AMDD**

In Minister of Health Regulation Number 62, 2017



Indonesia has ratified ASEAN MEDICAL DEVICE DIRECTIVE (AMDD) in 2018, 10 ASEAN Member states has harmonized their MD regulation

Asia-Pacific Economic Cooperation
Priotity Working Area: Medical Devices

World Health Organization
SEARN SOUTH-EAST ASIA REGULATORY NETWORK
Working Group5: Medical Device and IVD

GHWP
Working Group 5: Clinical evidence for performace and safety

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TERIMA KASIH

THANK YOU

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