KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

GERMAS
Gerakan Masyarakat Hidup Sehat

INDONESIA MEDICAL DEVICE REGULATION UPDATE

Directorate of Medical Devices and Household Health Products Evaluation
Directorate General of Pharmaceuticals and Medical Devices
MINISTRY OF HEALTH THE REPUBLIC OF INDONESIA
2021

INDONESIA PRE- AND POST-MARKET CONTROL OF MEDICAL DEVICES

Product Research and Development → Production → Registration/ product License → Advert isment → Distribution → Consumer → Disposal

PRE MARKET ← → POST MARKET

Manufacturer

- Manufacturer License
- GMP Certificate

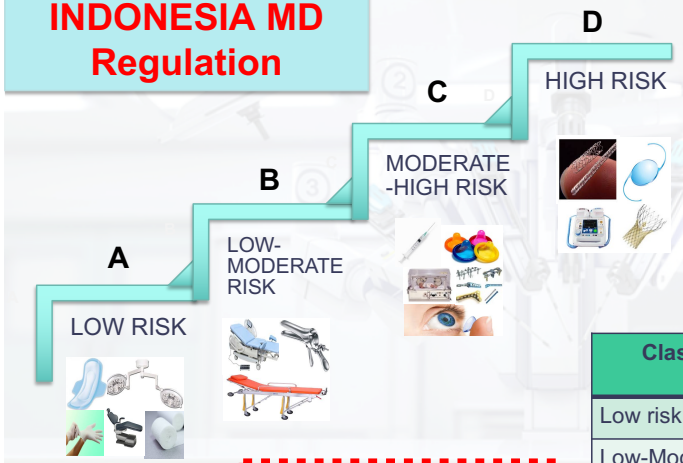
Product License

- Ensure the safety, quality and performance of MD

Distributor

- Distributor License
- GDP Certificate

INDONESIA MD Regulation



Indonesia has ratified ASEAN Medical Device Directives in 2018

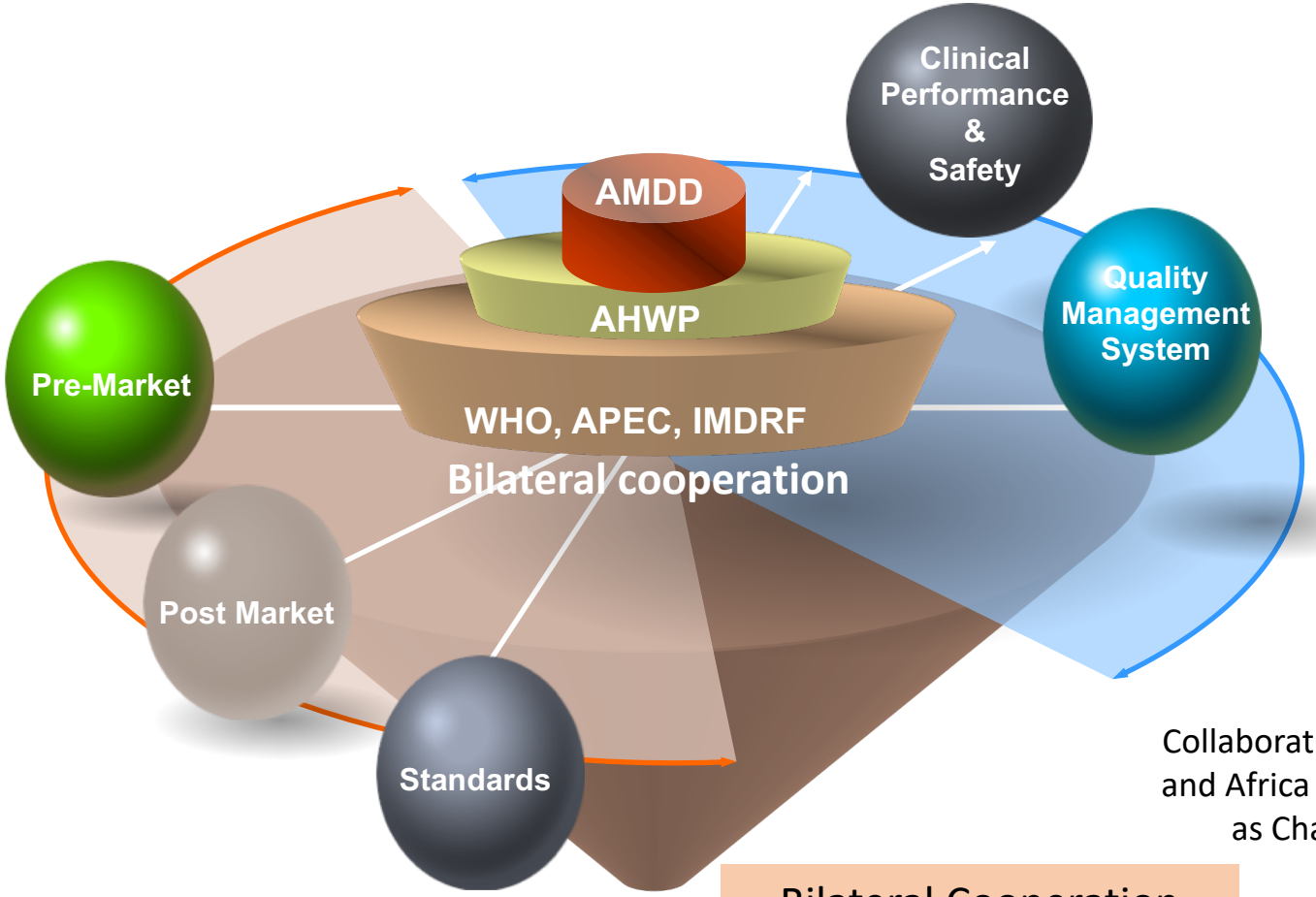
Classification	AMDD (ASEAN MED DEV DIRECTIVES)	EU
Low risk	A	I
Low-Moderate risk	B	IIa
Moderate-High risk	C	IIb
High risk	D	III

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

INDONESIA MEDICAL DEVICE REGULATION
BASED ON REGIONAL AND GLOBAL PRACTICES



Regional and multilateral cooperation

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

APEC
Asia-Pacific Economic Cooperation

Priotity Working Area: Medical Devices meliputi Pre-Market, Post-Market dan QMS

Indonesia as Chair of Asean Medical Device Technical Committee

AHWP
ASIAN HARMONIZATION WORKING PARTY

Collaboration with Asia, Middle East and Africa through AHWP. Indonesia as Chair of WG clinical trial

World Health Organization
SEARN SOUTH-EAST ASIA REGULATORY NETWORK

Collaboration with South East Asia countries for medical products with one of Working Group is Medical Device and IVD
Indonesia as Chair of WG Medical Device

Bilateral Cooperation

- USA
- Australia
- Netherland
- Brunei Darussalam
- Denmark
- India
- Iran
- Colombia
- South Korea
- Cuba
- Laos
- PNG
- Qatar
- Singapore
- Timor Leste
- China
- Turkey
- Vietnam
- Etc (MoU on progress)

Conducting and explore the market access opportunities through joint venture cooperation and Health Business Forum

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Main Duties and Functions

of the Directorate Medical Devices and Household Health Products Evaluation

- Preparation of policy formulation and implementation
- Formulation of norms, standards, procedures and criteria
- Technical guidance
- Evaluation and report preparation
- Implementation of administrative and household affairs

HEALTH LAWS NO. 36/2009

Article 106

Pharmaceutical and medical devices can only be circulated after obtaining a product license.

Article 104

Pharmaceutical and medical devices control are implemented to protect the public from the dangers caused by the use of pharmaceutical and medical devices that do not meet the requirements for quality and / or safety and / or efficacy / benefit.

Type of Licensing

- Medical Devices Product License
- Household Health Products License
- Certificate of Medical Devices and Household Health Products
  - Certificate of Free Sales (CFS)
  - Certificate of Exportation (CoE)
  - Import of Raw Materials
  - Product Information
  - Advertisement Approval

Online Registration Flow of Medical Devices and Household Health Products

Business Identification Number (NIB)
Through
Online Single Submission (OSS)
Investment Coordinating Board (BKPM)

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Manufacture and Distribution License
Directorate Medical Devices and Household Health Products Supervision
www.sertifikasialkes.kemkes.go.id

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Product License
Directorate Medical Devices and Household Health Products
Evaluation www.regalkes.kemkes.go.id

↓

Digital signature Certificate of Product License
of Medical Devices and Household Health Products

Medical Devices Product License Requirements

1. Production Certificate
2. Distribution Certificate
3. Letter of Authorization*
4. Certificate of Conformity
5. Executive Summary
6. Standards and Evidence of Standard Conformity
7. Trademark Patent Statement / Releasing Agency
8. Statement of Data Authenticity

1. Product Description
2. Description and Features of Medical Devices
3. The intended use
4. Indication
5. Instructions for use
6. Material and information of origin (local / import)
7. Production Process
8. Flowchart + QC Process

1. Finished product specifications
2. Additional information on product characteristics
3. Sterile process validation (if product is sterile)
4. Specifications and raw material requirements
5. Packaging specifications
6. Analysis Test Results : Clinical Trial Results, CoA finished products, and QC documents

1. Marking Plate /Packaging Design
2. Explanation of the marking plate /packaging design
3. IFU (English and Indonesian)
4. Production Code
5. List of Accessories
6. Other Supporting data

1. Complaint and Recall Handling Procedures and Forms

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REGULATIONS RELATED TO THE COVID-19 PANDEMIC SITUATION

Presidential Decree Number 9 of 2020

Amendment to Presidential Decree Number 7 of 2020 on Task Force for the Acceleration of Handling Corona Virus Disease 2019 (Covid-19).

Regulation of the Minister of Health Number 7 of 2020

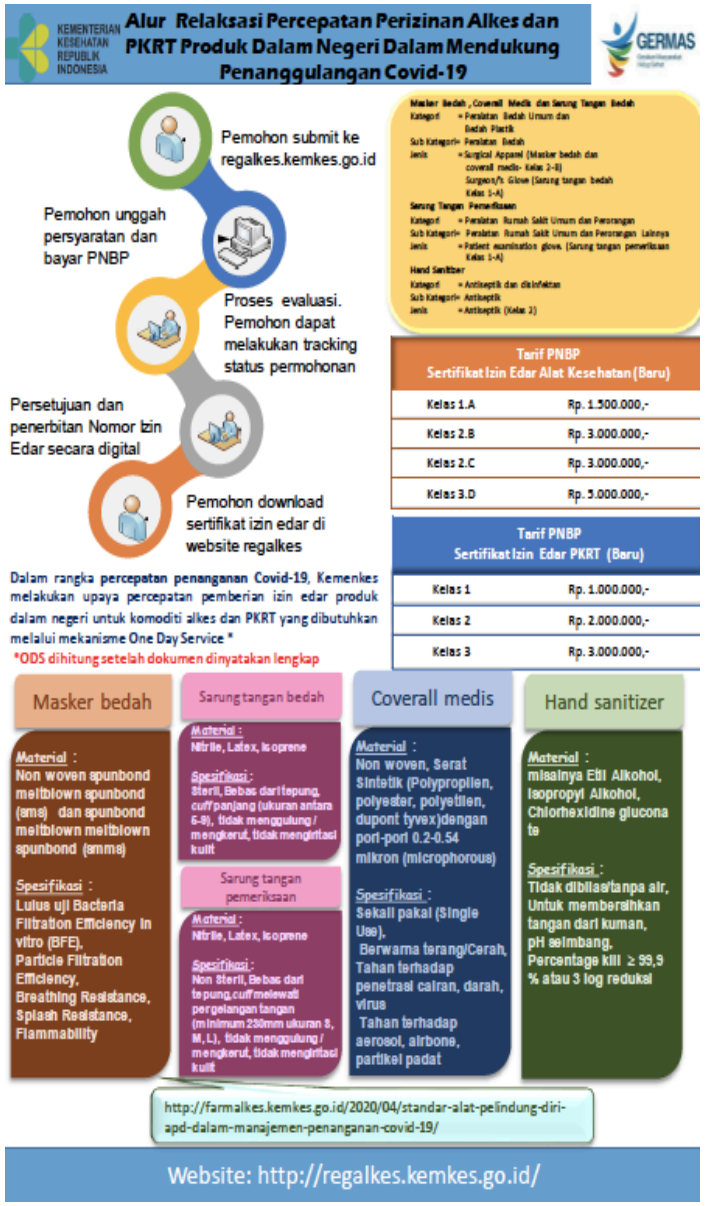
Amendment to Regulation of the Minister of Health Number 51 of 2020 on Entry of Medical Devices through Special Access Scheme

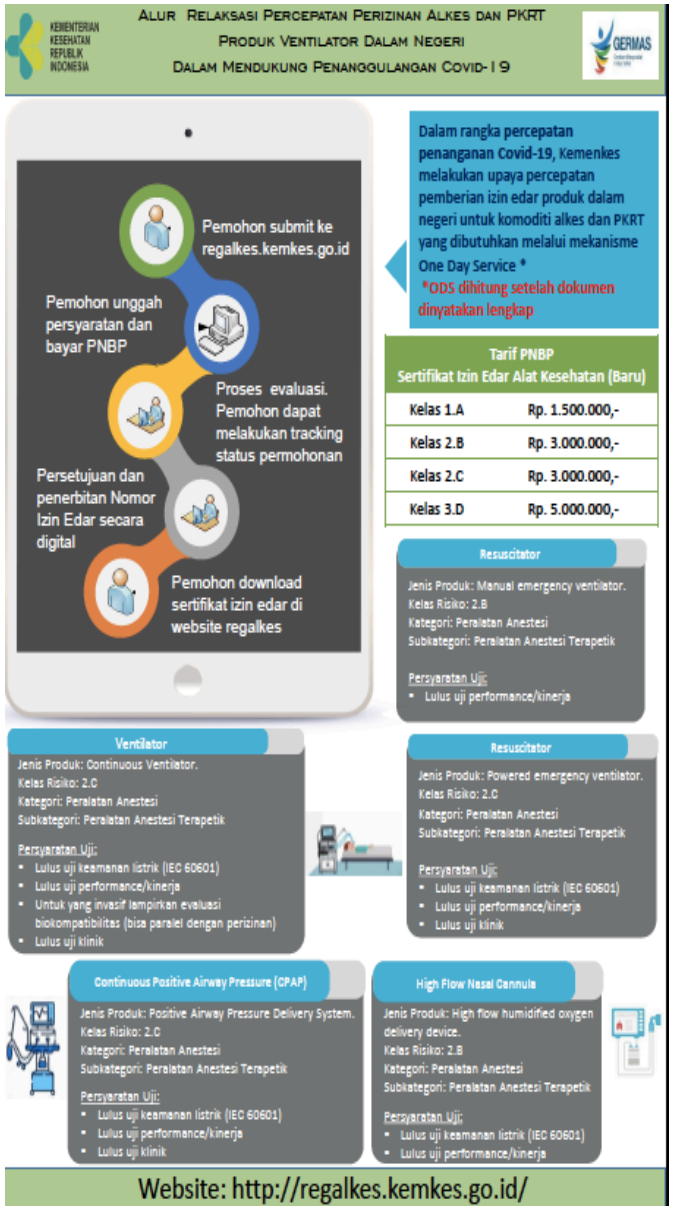
Minister of Health Decree Number HK.01.07/Menkes/218/2020

on Medical Devices, in Vitro Diagnostic Medical Devices and Household Health Products that are Exempted from the Import Business License in the Context of Combating COVID-19.

- **Accelerating the importation of products needed in handling Covid-19 through the exception of import trade system licensing**
- **Regulating the HS Code for Medical Devices needed in handling Covid-19**
- **Emergency Use Approval For Covid-19 Products**

RELAXATION OF MEDICAL DEVICE REGULATION DURING THE PANDEMIC OF COVID-19





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To encourage the availability of Medical Devices and Household Health Products needed in handling COVID-19

Especially for manufacturers or distributor of the following products:

- Surgical Face Mask and N95 Respirators
- Isolation Gown
- Liquid Chemical Sterilant/High Level Disinfectants,
- Surgeon's Glove dan Patient Examination Glove,
- Power Air Purifying Respirator,
- ECMO (Extracorporeal Membrane Oxygenation),
- Breathing Circuit for Ventilator and CPAP,
- Neonatal Incubator and Incubator Transport,
- Transport Culture Medium (VTM/UTM),
- Microbiological Specimen Collection and Transport Device (Dacron Swab)
- Device/Reagent/Rapid Diagnostic Test for COVID-19,
- Thermometer,
- Ventilator,
- Infusion Pump,
- Mobile X-Ray,
- High Flow Oxygen Device,
- Bronchoscopy Portable,
- CPAP Mask
- CPAP Machine,
- Resuscitation Bag
- Hand Sanitizer.

Policy Relaxation:

- Priority Service time acceleration after the file is complete
- Simplification of requirements
- Additional service days on Weekend and Public Holidays

01 ☑ **Medical Device Production Certificate**

02 ☑ **Household Health Products Production Certificate**

03 ☑ **Medical Device Distribution Certificate**

04 ☑ **Product License for Medical Devices and Household Health Products**

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Implementation of Medical Device Control During The New Normal Era

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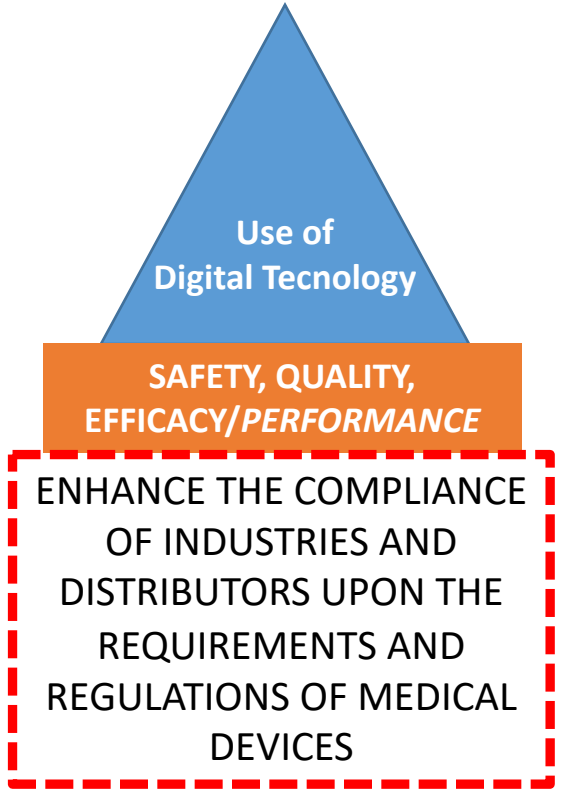
***Pre market Control* in the New Normal Era:**

- Optimize the use of digital information technology in the process of licensing (facility and product license).
- Focus on new medical device innovation.
- Adjustment the requirement in the new normal condition (*clinical evaluation*, Certificate of Free Sales, Letter of Authorization and supported documents).
- Easiness and flexibility of consultation/assistance through virtual system.



***Post market Control* in the New Normal Era :**

- Conducting remote audit to production and distribution facilities.
- The use of information and technology to conduct Monitoring/vigilance.
- Optimize the use of electronic based reporting (*e-report* and *e-watch*)
- Conducting medical device product Sampling through the online courier services.

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Please Visit these website to access information and guidelines

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Product license/registration
www.regalkes.kemkes.go.id

Production and distribution license
www.sertifikasialkes.kemkes.go.id

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TERIMA KASIH

THANK YOU

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