KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

# Indonesian Medical Device Landscape Transformation

22 June 2022

Each of us has a crucial role in ensuring that the next generation is healthy, well-educated, and productive.

# MoH is committed to implementing health system transformation

## Six pillars of health transformation

**Vision**

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

**Health system outcomes**

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

**6 main pillars**

### 1 Primary Care Transformation

**a Population Education**

7 main campaigns: immunization, balanced nutrition, sports, no-smoking movement, sanitation, disease screening, and medical compliance

**b Primary prevention**

adding the scope of 14 routine immunization and to all regions in Indonesia

**c Secondary prevention**

Health screening for 14 leading diseases causing death in each age target, stunting screening, & improving ANC for maternal and baby health.

**d Improving capacity and capability of primary care**

Developing Puskesmas in 171 sub-districts, provision of 40 essential med, adding health workers in primary care

### 2 Secondary Care Transformation

**Increasing access and quality of secondary health care**

Constructing hospitals in eastern areas, mentoring network of 6 priority care, partnership with *world's top healthcare centers.*

### 3 Health System Resilience Transformation

**a Improving resilience of pharma and med-devices sector**

Local production of 14 routine vaccines, top 10 med, top 10 med-devices *by volume & by value.*

**b Strengthening emergency response resilience**

national network of lab based surveillance, additional workers for emergency response,, *table top exercise of crisis preparedness.*

### 4 Health financing Transformation

Health financing regulation with 3 goals: accessible, sufficient, and sustainable; equitable allocation; and effective-efficient utilization

### 5 Health Talent Transformation

Adding med students quota, local and international scholarship, easy access for abroad medical graduates for adaptation process.

### 6 Health Technology Transformation

Development and usage of technology, digitalization, and bio-technology in health sector.

a Information technology

b Biotechnology

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

Pilar 3

# Health System Resilience

Local production of pharma and medical devices and the emergency response resilience

# Strategy for the resilience of pharmaceutical, medical devices, and emergency response

## Vaccines

- Production of **7 out of 14** types of antigens for the **routine immunization vaccines** and **tuberculosis program**
- Mastery of **viral-vector** and **nucleic acid based** technologies

## Pharmaceutical

- Production of **6 out of 10** highest consumption **pharmaceutical raw materials / active pharmaceutical ingredients (API)**
- Production of **biopharmaceutical** and **plasma derivatives**

## Medical Devices

- Increase purchases of **16 out of 19** top **medical devices** by volume and value produced in Indonesia
- Production of **high-tech medical devices (3 out of 19)**

## Emergency Response

- Registered and trained emergency team

| | 2022 | 2023 | 2024 | 2025 |
|---|---|---|---|---|
| Vaccines | | 1. Measles<br>2. Rubella<br>3. Rotavirus<br>4. TBC | 5. HPV<br>6. PCV | 7. IPV<br>8. JE |
| | | mRNA vaccine | Viral vector vaccine | |
| | | Technology transfer through B2B, international organization, and multilateral cooperation | | |
| Pharmaceutical | 1. Candesartan<br>2. Bisoprolol | 3. Amlodipine<br>4. Lansoprazole | 5. Cefixime<br>6. Ceftriaxone | |
| | EPO, Insulin, m-Ab (Bevacizumab), *Stem Cell* | m-Ab (Tocilizumab), HyFC-EPO | Plasma Derivatives (Albumin, IVIg, F-VIII), m-Ab (Adalimumab, Rituximab, PD-1), R-Insulin | |
| Medical Devices | Local content (TKDN) of medical devices | | | 1. CT Scan<br>2. Endoscopy<br>3. MRI |
| Emergency Response | Initiate cooperation | Training and certification | 100% registered and trained emergency team | |

# Local production of top 10 medical devices by volume and by value

**16** out of **19** top value medical devices can be produced locally, while **3** are still dependent on import

| No | By Volume | By Value |
|---|---|---|
| 1 | Piston syringe | Continuous ventilator (non invasive & invasive/ICU) |
| 2 | Intravascular administration set | Cardiac monitor (including cardiotachometer and rate alarm) |
| 3 | Surgeon's glove | **CT Scan / Computed tomography x-ray system** |
| 4 | Intravascular catheter | **Endoscope and accessories** |
| 5 | Gauze & wound dressing | Mobile x-ray system |
| 6 | Specimen transport and storage container | AC & manual hospital bed |
| 7 | Hypodermic single lumen needle | **MRI / Magnetic resonance diagnostic device** |
| 8 | Alcohol swab | Piston syringe |
| 9 | Blood specimen collection device | Stationary x-ray system |
| 10 | Surgical mask, coverall, surgical gown, shoe cover, cap, medical goggles / Surgical apparel | USG / Ultrasonic pulsed doppler imaging system |

**Fully dependent on import**

Low production capacity

Source: LKPP e-Catalogue 2019-2020

# Policy to promote the resiliency of pharmaceutical and medical devices

## Research & development

- ***Task force*** to develop R&D ecosystem
- Facilitate **technology transfer**
- Facilitate **clinical trial for vaccine** (especially Merah Putih Vaccine)
- Facilitate **clinical trial for medical devices**
- Facilitate the ***change source*** of pharmaceutical raw materials / active pharmaceutical ingredient (API)

## Production

- **Intervention through incentives and disincentives** for pharma and medical devices industries
- **Simplification of permission process**
- **Facilitate testing and calibration** performance and use of medical devices

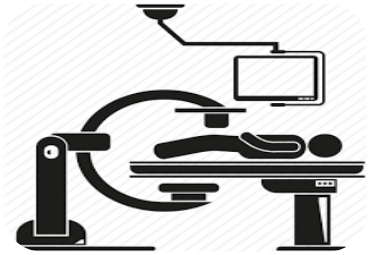
## Market protection

- **Substitution of imported products:** Freezing imported products in the e-catalog that can be produced locally and are able to meet national demand
- **Implementation of domestic component level / local content (TKDN) policy:** prioritizing pharmaceutical and medical devices product with high domestic component level / local content (TKDN) in the procurement of goods and services
- **Implementation of Increased Use of Domestic Product (P3DN) program** especially in the government / public hospitals (vertical and regional) and private hospitals

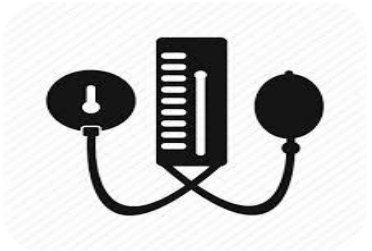
# Regulatory Convergence and Harmonization

# Strengthening regulatory capacity to ensure access to affordable medical products that are safe, of good quality and effective

Technologies, Standards, Norms



Regulatory System Strengthening



Safety and Vigilance

**Decreased regulatory burden**

**Reduced time for regulation**

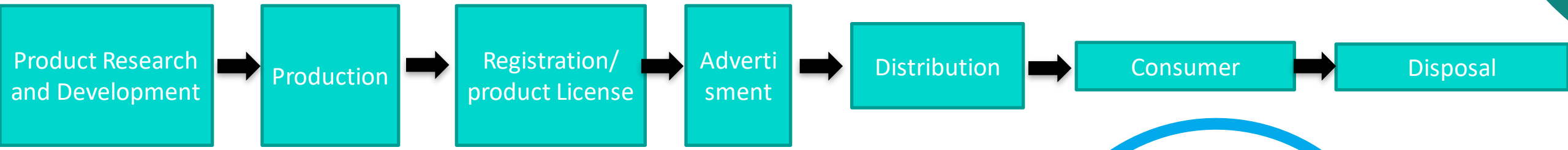
**Increased regulatory capacity**

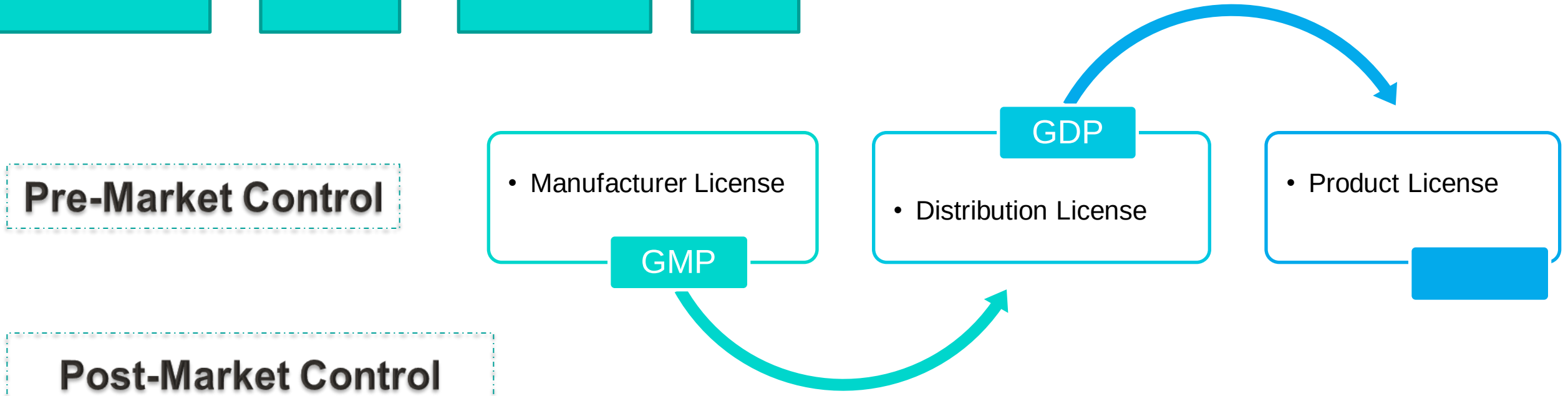
**Decreased cost of regulation**

**Reduced mortality and morbidity**

# Regulation on Medical Device Sector

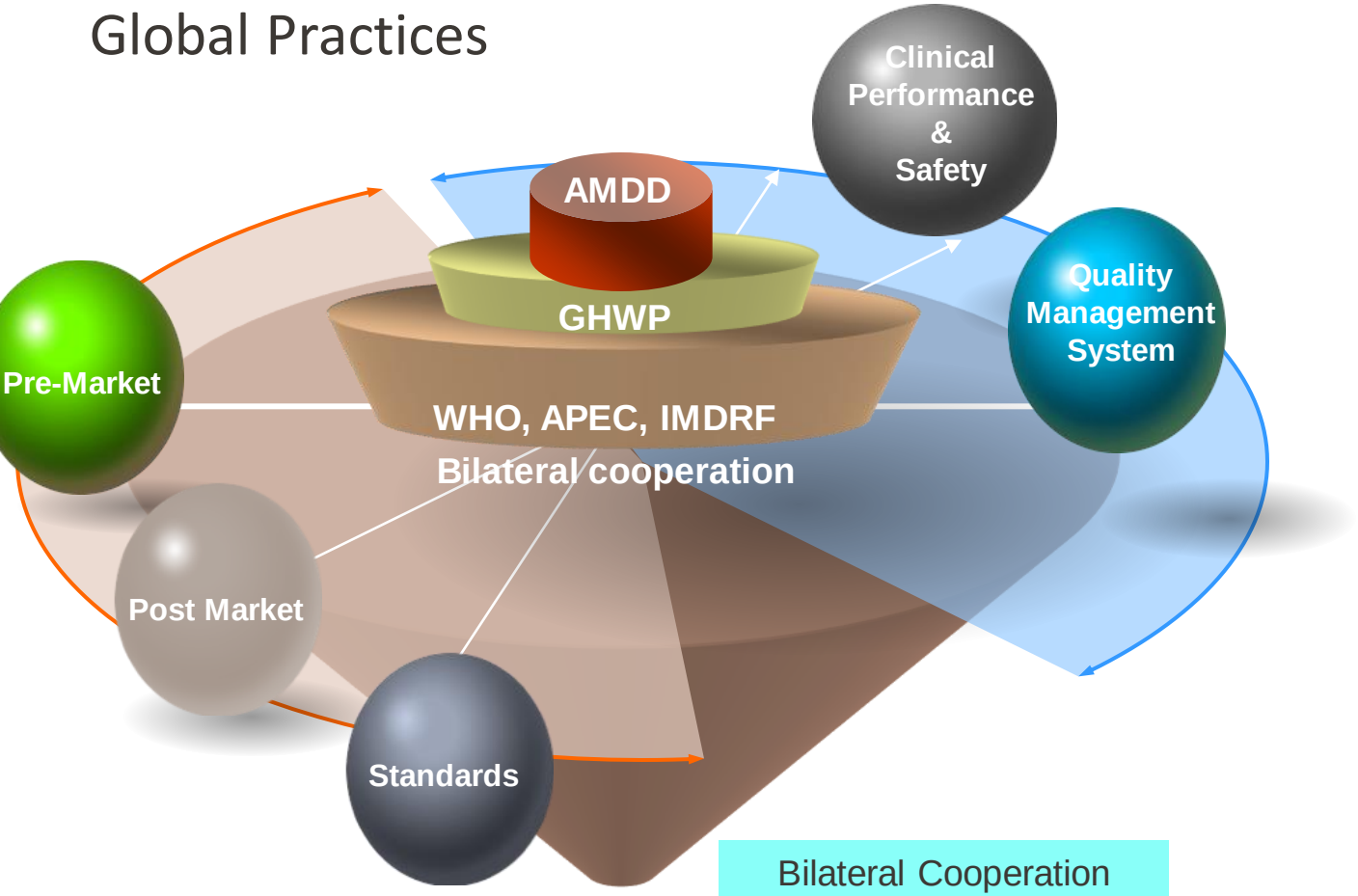
- Pre and Post Market Control




# Regulation on Medical Device Sector

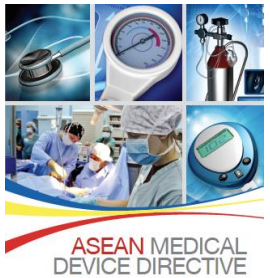
- Indonesia Medical Device Regulation Based on Regional and Global Practices




## 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)

## Regional and multilateral cooperation




Indonesia has ratified ASEAN MEDICAL DEVICE DIRECTIVE (AMDD).

**Asia-Pacific Economic Cooperation**

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

**GHWP**

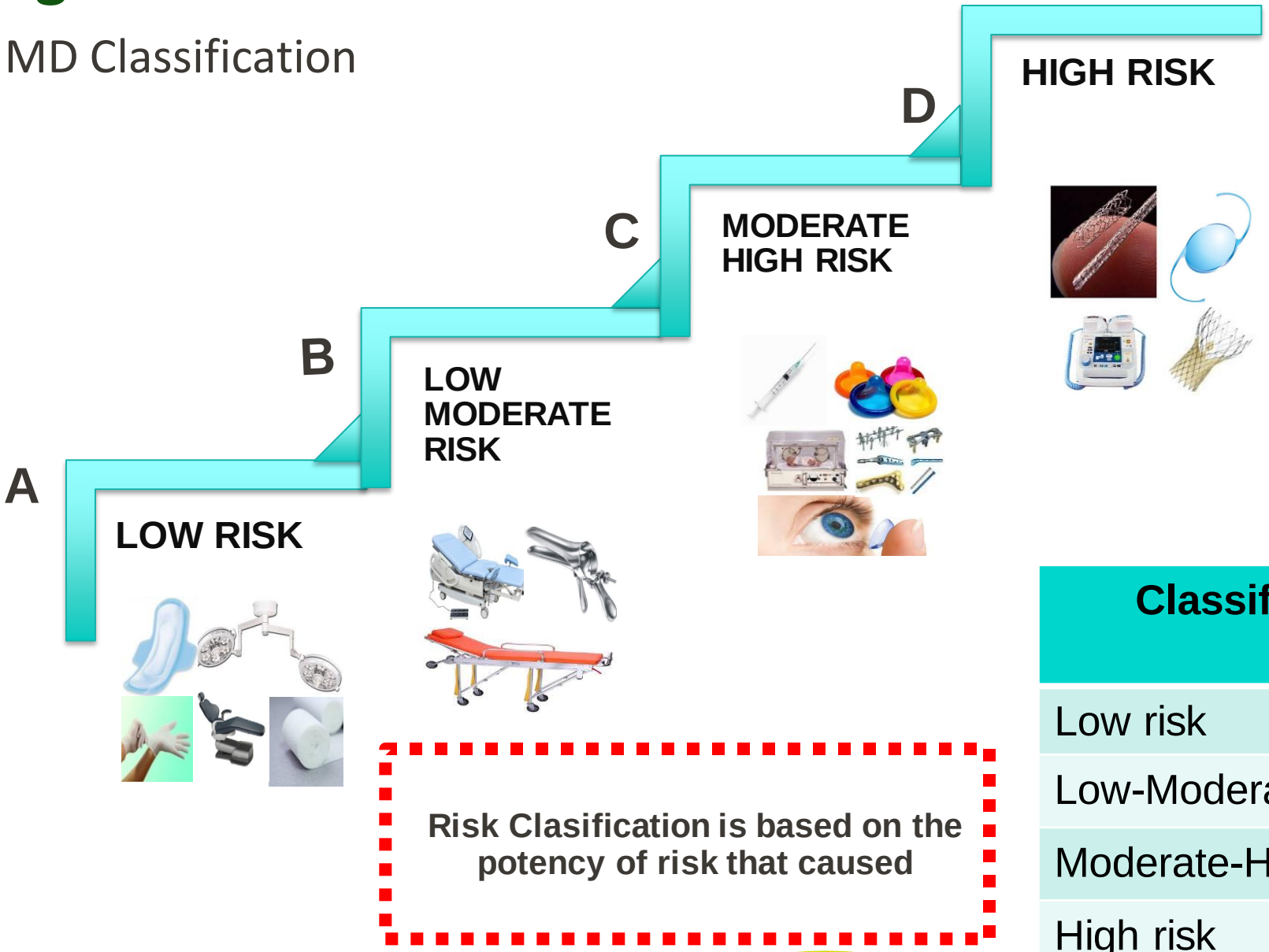
Collaboration with Asia, Middle East and Africa through GHWP.

**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.

# Regulation on Medical Device Sector

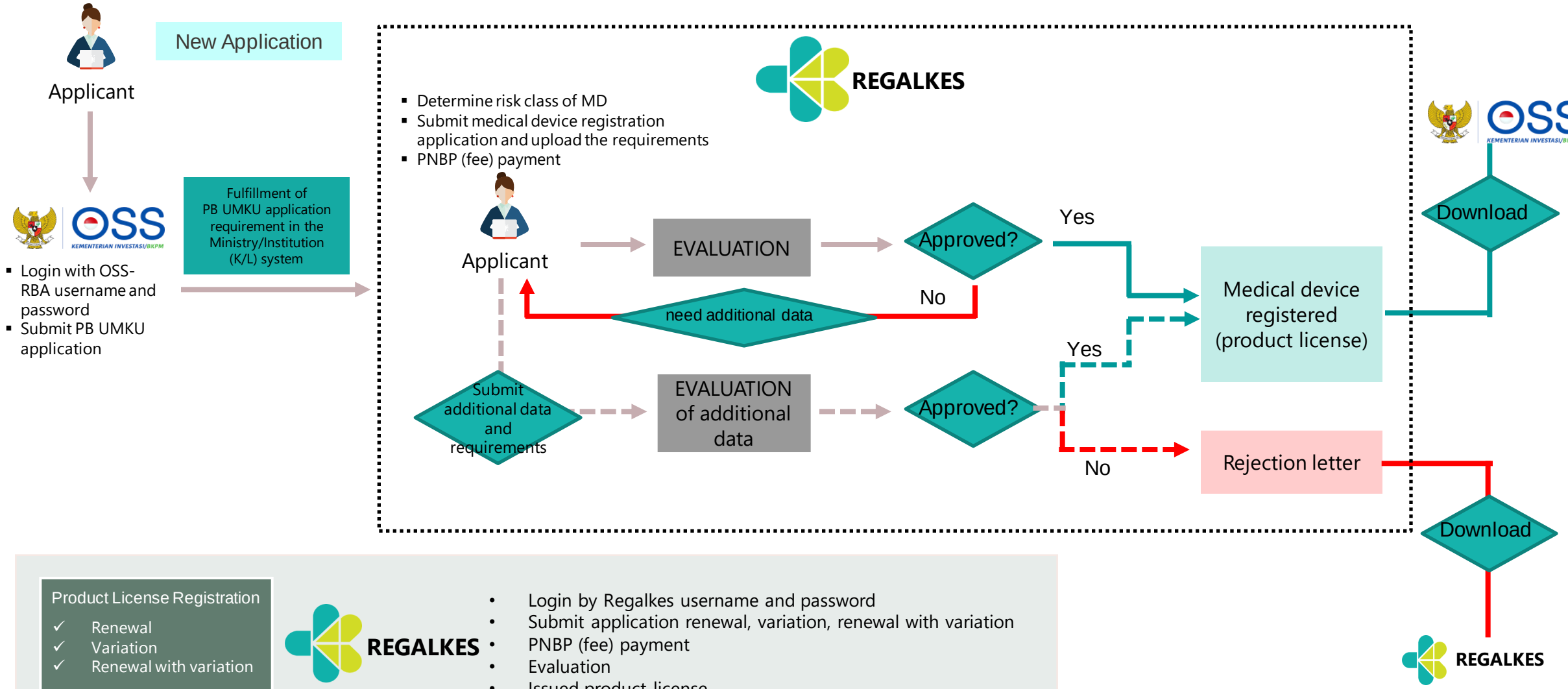
- MD Classification




**Risk Clasification is based on the potency of risk that caused**

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

# Overview of Medical Device Registration




**Product License Registration**

- ✓ Renewal
- ✓ Variation
- ✓ Renewal with variation

**REGALKES**

- Login by Regalkes username and password
- Submit application renewal, variation, renewal with variation
- PNBP (fee) payment
- Evaluation
- Issued product license

# Medical Device Registration

Submitted by:

**Manufacturer**

Production License/ Standard Certificate

**Distributor**

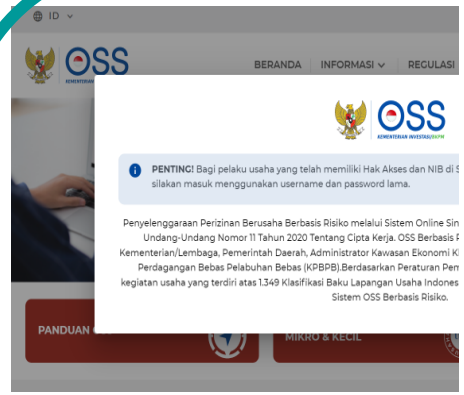
Distribution License

## Notification

- Certain low risk medical device (class A)
- SLA <<
- Requirements <<

## Regular

- Class A in general
- Class B, C, D
- SLA>>
- Requirement >>

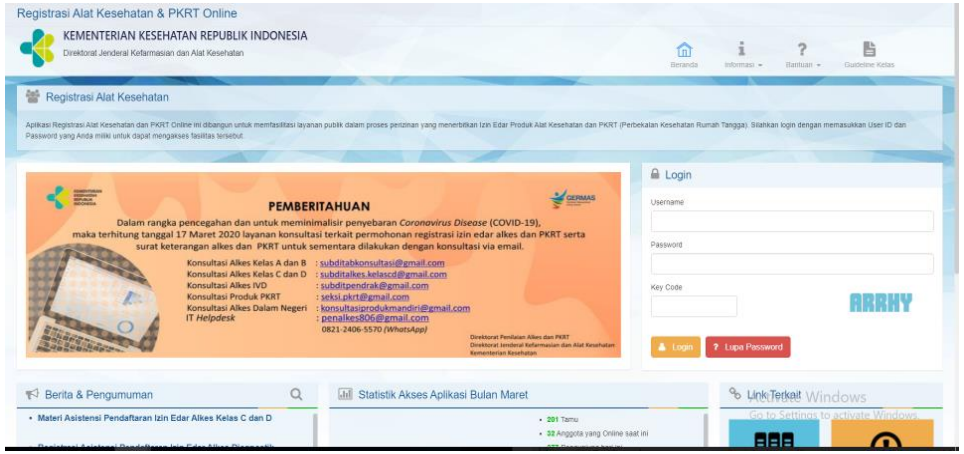



OSS
KEMENTERIAN INVESTASI/BKPM

Online Single Submission (OSS) adalah sistem perizinan berusaha terintegrasi secara elektronik yang dikelola dan diselenggarakan oleh Lembaga OSS (Kementerian Investasi/BKPM). Dengan semangat Undang-Undang Cipta Kerja, kini sistem OSS melayani perizinan berusaha berbasis risiko. Melalui sistem OSS, perizinan berusaha menjadi pasti, mudah, efektif, dan transparan.

Kembali ke Halaman Beranda OSS

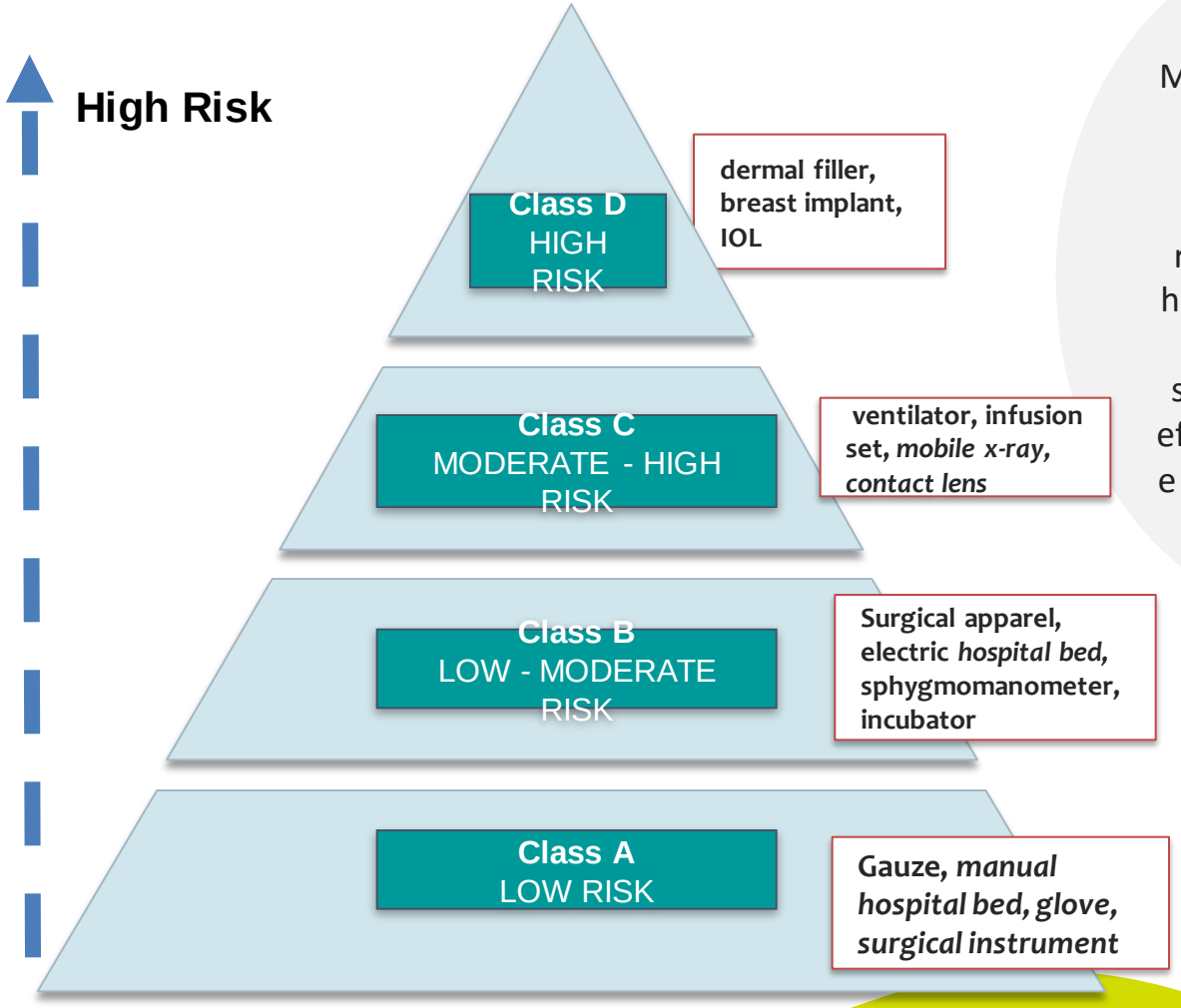
**https://oss.go.id/**




**http://regalkes.kemkes.go.id/**

# MEDICAL DEVICE REGISTRATION

## Indonesia Medical Device Classification




Medical devices risk classification determines the registration requirements that has to be submitted to ensures the safety, quality and efficacy/performanc e of medical devices

## Service Level Agreement (SLA) of MEDICAL DEVICES

### New Registration

| Medical Device Class | Evaluation timeline (maximum of working days) | | Registration Fee |
|---|---|---|---|
| | Local Product | Imported Product | |
| A | 10 | 15 | IDR 1.500.000 (±USD 105) |
| B | 20 | 30 | IDR 3.000.000 (±USD 210) |
| C | 20 | 30 | IDR 3.000.000 (±USD 210) |
| D | 30 | 45 | IDR 5.000.000 (±USD 350) |

*1 USD = ± IDR 14300

### Registration for renewal , variation, or renewal with variation

| Medical Device Class | Evaluation timeline (maximum of working days) | | Registration Fee | |
|---|---|---|---|---|
| | Renewal | Variation or renewal w/ variation | Renewal/ Variation | Renewal w/ variation |
| A | 7 | 10 | IDR 500.000 (± USD 35) | IDR 1.000.000 (±USD 70) |
| B | 7 | 10 | IDR 1.000.000 (±USD 70) | IDR 1.500.000 (±USD 105) |
| C | 7 | 10 | IDR 1.000.000 (±USD 70) | IDR 1.500.000 (±USD 105) |
| D | 7 | 10 | IDR 1.000.000 (±USD 70) | IDR 1.500.000 (±USD 105) |

**Evaluation of additional data /information maximum 10 working days except 7 working days for renewal application**

# Indonesia CSDT Format

**ASEAN CSDT FORMAT (from AMDD)**

- Executive summary
- Essential Principles & Evidence of Conformity
- Device Description
- Design Verification & Validation
- Clinical Evidence
- Device Labelling
- Risk Analysis
- Manufacturer Information

**INDONESIA CSDT FORMAT**

- Form A: Administration data
- Form B: Product information
- Form C: Specification and Quality Assurance
- Form D: Labelling
- Form E: Post Market Evaluation

Indonesia Registration Forms

→ Requirements for product license

"The adoption of the ASEAN CSDT in Indonesia arranged in different formats but with essentially the same contents"

# REQUIREMENTS OF MEDICAL DEVICE REGISTRATION

## FORM A
Administration

1. Production license/Standard Certificate
2. Distribution license
3. Letter of authorization
4. Certificate of free sale
5. Quality management system certificate and certificate of conformity (ISO 13485, CE)
6. Executive summary
7. Declaration of conformity
8. Trademark patent statement / releasing agency
9. Statement of data authenticity
10. Statement of integrity

## FORM B
Product Information

1. Product Description
2. Description and Features of Medical Devices
3. Intended purpose
4. Indications
5. Instructions for use
6. Contraindications
7. Warnings
8. Precautions
9. Potential adverse effects
10. Alternative therapy
11. Material
12. Information about manufacturer
13. Manufacturing and QC Process

## FORM C
Specification and Quality Assurance

1. Product specifications
2. Additional information on product characteristics
3. Sterile process validation
4. Pre-clinical studies
5. Software validation
6. Biological material information
7. Clinical evidence
8. Risk analysis and result
9. Raw material specification and requirement
10. Packaging specifications
11. Stability
12. Testing (IEC), specification, CoA products, and QC documents

## Form D
Labelling

1. Medical device labelling (ex. artwork design, label, packaging, marking plate)
2. Explanation packaging design and symbol
3. Instruction of use - Indonesian and English version
4. *Lot numbering System*
5. Accessories

## Form E
Post Market Evaluation

Complaint and recall handling system and procedures

Additional test by accredited laboratories in Indonesia for following product:

1. Condom
2. Sterile gauze
3. Sterile Syringe
4. Radiology products (which contain/emit ionizing radiation)

# NOTIFICATION

- Product license registration with **notification** only applied to **certain class A** medical device which is **home-use** and **non sterile class A** medical device that can be used independently **without any professional or special skill/ healthcare professional assistance**.
- Notification also doesn't apply to in vitro diagnostic product.
- Simplification of marketing authorization/ product license

| Medical device registration by notification | | |
|---|---|---|
| Arm sling | Ice bag | Ophthalmic eye shield |
| Body waste receptacle | Limb orthosis | OTC Denture cleanser |
| Cane | Nipple shield | Patient scale |
| Cane, crutch, and walker tips and pads. | Medical adhesive tape and adhesive bandage | Protective garment for incontinence |
| Medical disposable bedding | Mechanical wheelchair | Nonresorbable gauze/sponge for external use |
| Crutch | Mechanical Walker | Stand-on patient scale |
| Dental floss | Manual toothbrush | teething ring |
| Elastic bandage | Cold pack | Therapeutic massager |
| Flotation cushion | Medical insole | Truncal orthosis |
| Hernia support | Moist heat pack | menstrual pad |
| Hot or cold disposable pack | Manual breast pump | Hot/cold water bottle |

# NOTIFICATION

## Requirements

**Administration requirement**

- Production/Distribution License
- Quality Management Certification (ISO 13485, ISO 9001, CE)
- Letter of Authorization
- Certificate of Free Sale (imported product)

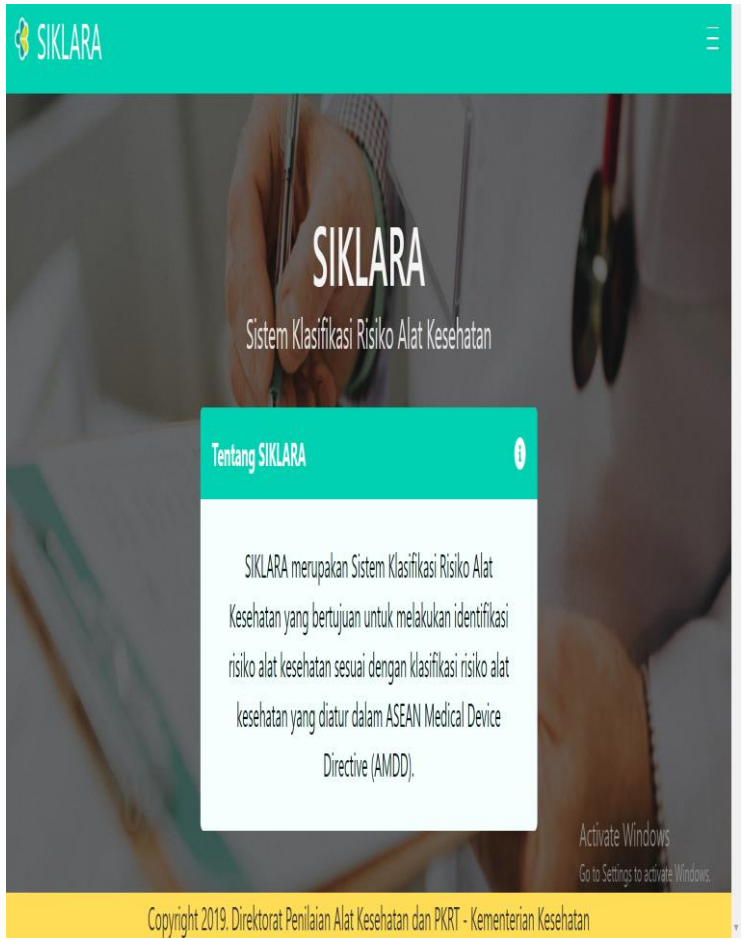
**Technical Requirement:**

- Material
- Product Specification
- Labelling and IFU
- Accessories (if applicable)

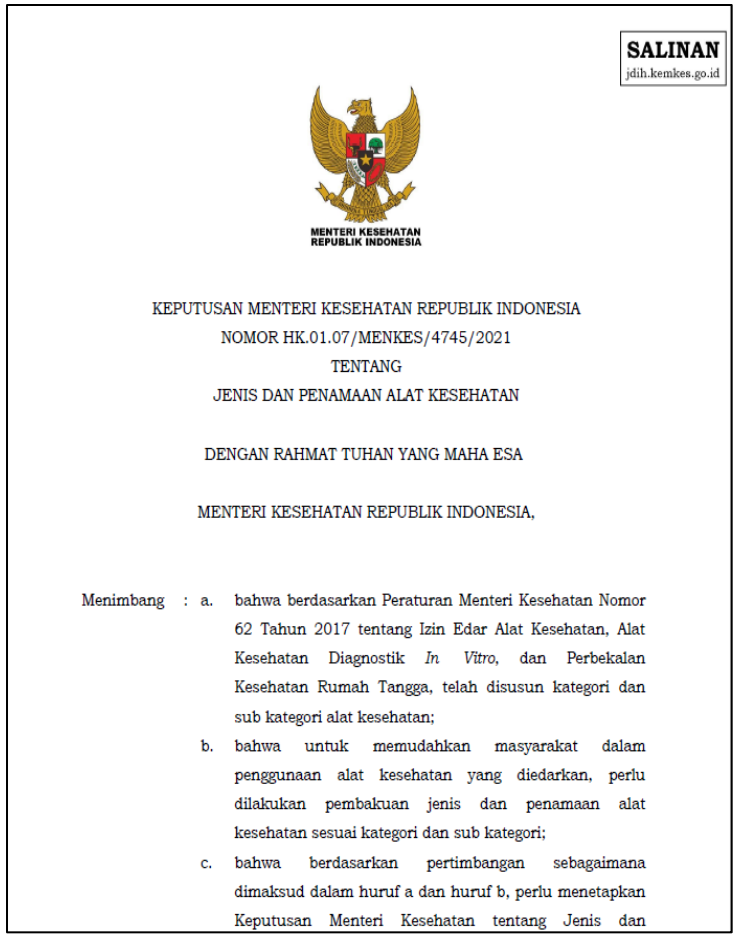
## Class A Medical Device Registration

| DIFFERENCE | Class A (Regular) | Class A (Notification) |
|---|---|---|
| Evaluation of new application | 15 working days | 6 working days |
| Evaluation of renewal application | 7 working days | 6 working days |
| Evaluation of variation and renewal with variation application | 10 working days | 6 working days |
| Registration Fee | same | |

# Guidance On Medical Device Registration




**Risk Classification Tool – SIKLARA**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KEPUTUSAN MENTERI KESEHATAN REPUBLIK INDONESIA
NOMOR HK.01.07/MENKES/4745/2021
TENTANG
JENIS DAN PENAMAAN ALAT KESEHATAN

DENGAN RAHMAT TUHAN YANG MAHA ESA

MENTERI KESEHATAN REPUBLIK INDONESIA,

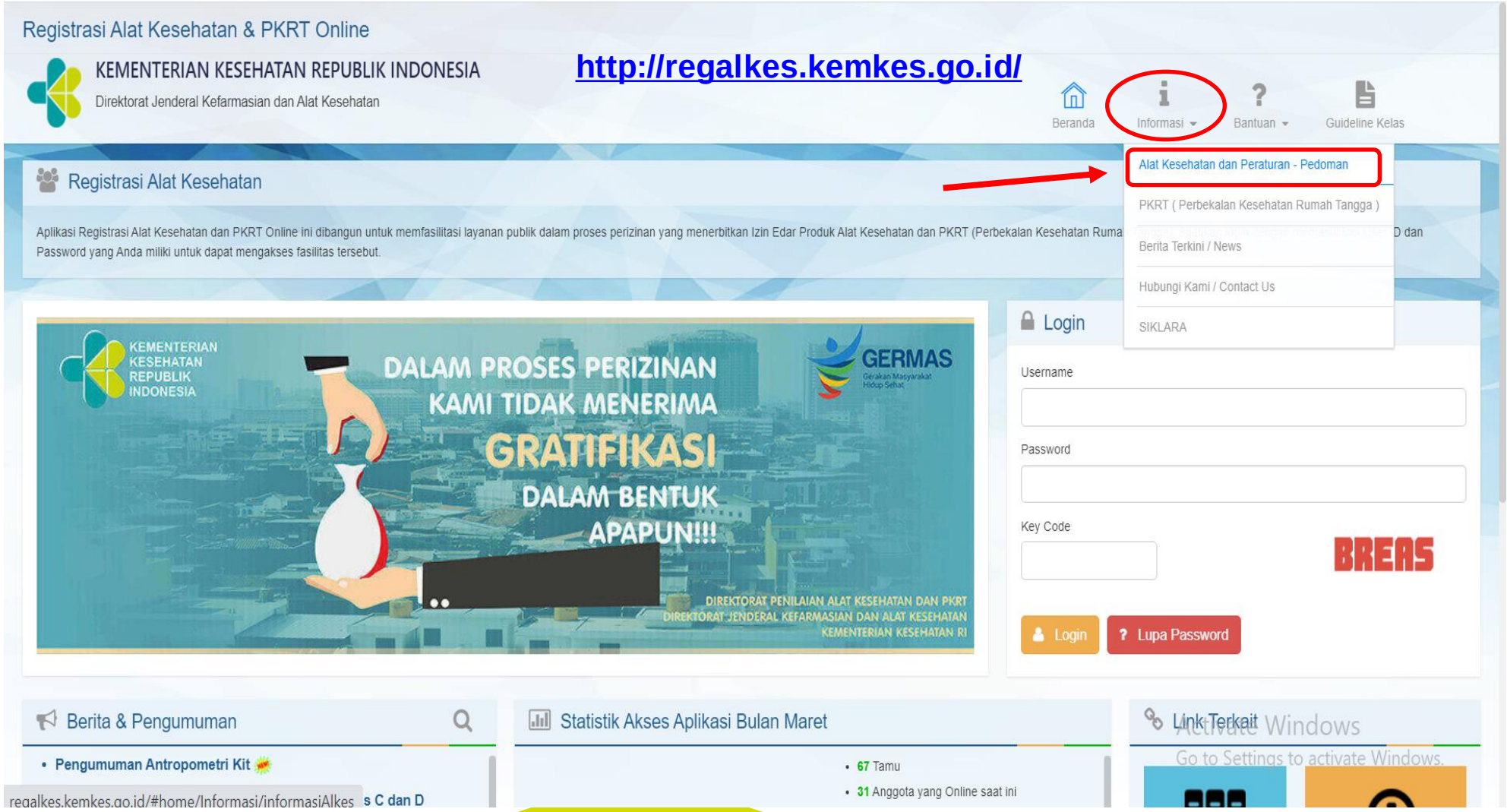
Menimbang : a. bahwa berdasarkan Peraturan Menteri Kesehatan Nomor 62 Tahun 2017 tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik *In Vitro*, dan Perbekalan Kesehatan Rumah Tangga, telah disusun kategori dan sub kategori alat kesehatan;

b. bahwa untuk memudahkan masyarakat dalam penggunaan alat kesehatan yang diedarkan, perlu dilakukan pembakuan jenis dan penamaan alat kesehatan sesuai kategori dan sub kategori;

c. bahwa berdasarkan pertimbangan sebagaimana dimaksud dalam huruf a dan huruf b, perlu menetapkan Keputusan Menteri Kesehatan tentang Jenis dan

**KMK 4475/2021 - related risk class and type of medical device**


**Medical Device Product Registration Guidelines**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Direktorat Jenderal Kefarmasian dan Alat Kesehatan
http://regalkes.kemkes.go.id/
Beranda
Informasi
Bantuan
Guideline Kelas
Alat Kesehatan dan Peraturan - Pedoman
PKRT ( Perbekalan Kesehatan Rumah Tangga )
Berita Terkini / News
Hubungi Kami / Contact Us
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Password yang Anda miliki untuk dapat mengakses fasilitas tersebut.
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DALAM PROSES PERIZINAN
KAMI TIDAK MENERIMA
GRATIFIKASI
DALAM BENTUK
APAPUN!!!
GERMAS
Gerakan Masyarakat Hidup Sehat
DIREKTORAT PENILAIAN ALAT KESEHATAN DAN PKRT
DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN
KEMENTERIAN KESEHATAN RI
Login
Username
Password
Key Code
BREAS
Login
Lupa Password
Berita & Pengumuman
Pengumuman Antropometri Kit
Statistik Akses Aplikasi Bulan Maret
67 Tamu
31 Anggota yang Online saat ini
Link Terkait
Activate Windows
Go to Settings to activate Windows.

# Together we can build a stronger and healthier Indonesia

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