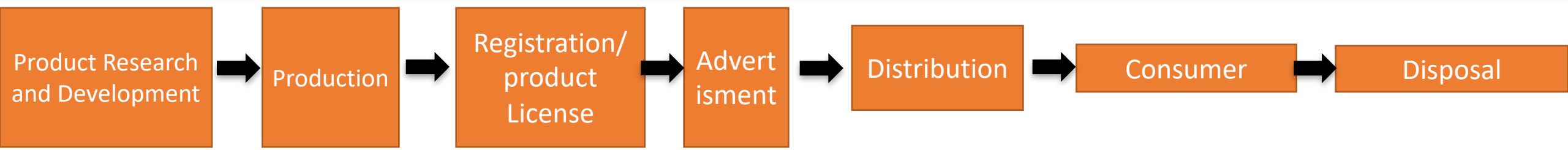


INDONESIA MEDICAL DEVICE REGULATION UPDATE

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



← PRE MARKET →

← POST MARKET →

Manufacturer

- Manufacturer License
- GMP Certificate

Product License

- Ensure the safety, quality and performance of MD

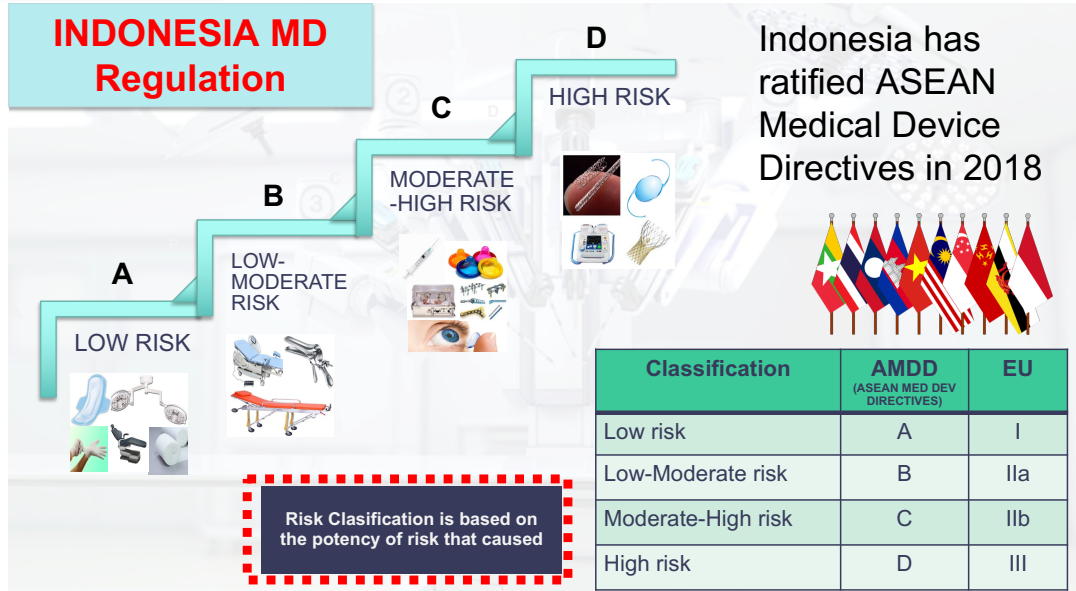
Distributor

- Distributor License
- GDP Certificate

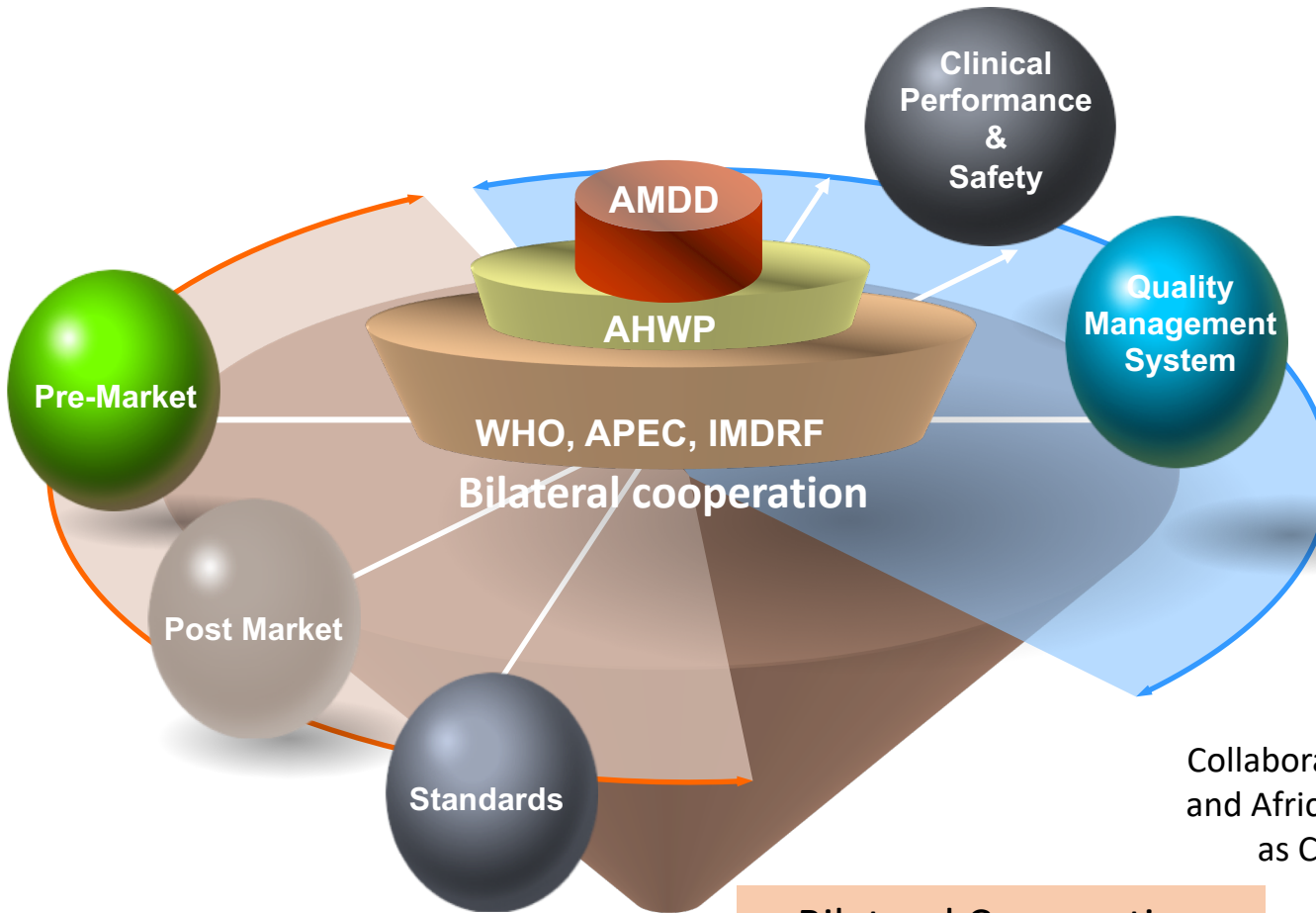
Post Market Control :



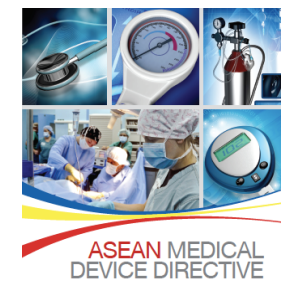
INDONESIA MD Regulation



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.



Asia-Pacific Economic Cooperation
Priority Working Area: Medical Devices meliputi Pre-Market, Post-Market dan QMS

Indonesia as Chair of Asean Medical Device Technical Committee



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



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

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

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)



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



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

REGULATIONS RELATED TO THE COVID-19 PANDEMIC SITUATION

Presidential Decree Number 9 of 2020

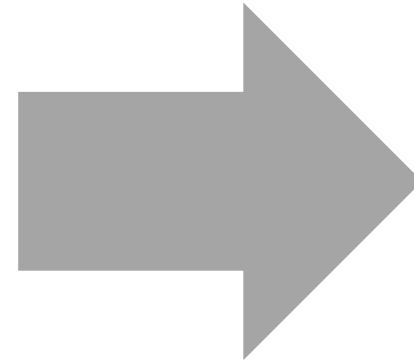
Amendment to Presidential Decree Number 7 of 2020 on Task Force for the Acceleration of Handling Corona Virus Disease 2019 (Covid-19).

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

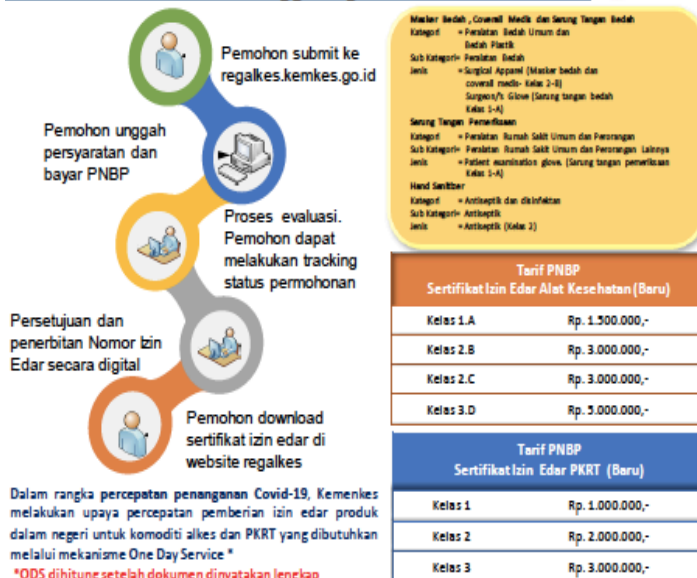
on Medical Devices, in Vitro Diagnostic Medical Devices and Household Health Products that are Exempted from the Import Business License in the Context of Combating COVID-19.



- **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

Alur Relaksasi Percepatan Perizinan Alkes dan PKRT Produk Dalam Negeri Dalam Mendukung Penanggulangan Covid-19



Masker Bedah, Coverall Medis dan Sarung Tangan Bedah
 Kategori: Perlatan Bedah Umum dan Bedah Plastik
 Sub kategori: Perlatan Bedah
 Jenis: Surgical Apparel (Masker bedah dan coverall medis kelas 2-4)
 Sarung Tangan: Sarung tangan bedah kelas 1-4

Sarung Tangan Pemeriksaan
 Kategori: Perlatan Rumah Salih Umum dan Perangan
 Sub kategori: Perlatan Rumah Salih Umum dan Perangan Lainnya
 Jenis: Sarung examination gloves (Sarung tangan pemeriksaan kelas 1-4)

Hand Sanitizer
 Kategori: Antiseptik dan disinfektan
 Sub kategori: Antiseptik
 Jenis: Antiseptik (Kelas 3)

Tarif PNBP Sertifikat Izin Edar Alat Kesehatan (Baru)	
Kelas 1.A	Rp. 1.500.000,-
Kelas 2.B	Rp. 3.000.000,-
Kelas 2.C	Rp. 3.000.000,-
Kelas 3.D	Rp. 5.000.000,-

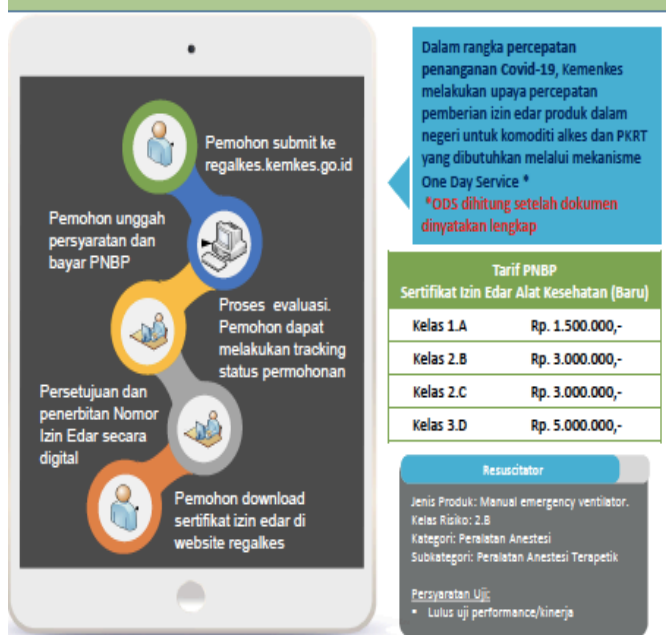
Tarif PNBP Sertifikat Izin Edar PKRT (Baru)	
Kelas 1	Rp. 1.000.000,-
Kelas 2	Rp. 2.000.000,-
Kelas 3	Rp. 3.000.000,-

<p>Masker bedah</p> <p>Material: Non woven spunbond meltblown spunbond (sms) dan spunbond meltblown meltblown spunbond (mms)</p> <p>Spesifikasi: Lulus uji Bacteria Filtration Efficiency in vitro (BFE), Particle Filtration Efficiency, Breathing Resistance, Splash Resistance, Flammability</p>	<p>Sarung tangan bedah</p> <p>Material: Nitrile, Latex, Isoprene</p> <p>Spesifikasi: Steril, Bebas dari papung, cuff panjang (ukuran antara 5-8), tidak mengumpul/mengkerut, tidak mengiritasi kulit</p>	<p>Coverall medis</p> <p>Material: Non woven, Serat Sintetis (Polypropylen, polyeter, polyetilen, dupont tyvek) dengan pori-pori 0.2-0.54 mikron (microphorous)</p> <p>Spesifikasi: Sekali pakai (Single Use), Berwarna terang/cerah, Tahan terhadap penetrasi cairan, darah, virus Tahan terhadap aerosol, airborne, partikel padat</p>	<p>Hand sanitizer</p> <p>Material: misalnya Etil Alkohol, Isopropyl Alkohol, Chlorhexidine gluconate</p> <p>Spesifikasi: Tidak diblasi/lempa air, Untuk memberahkan tangan dari kuman, pH seimbang, Persentase kill > 99,9 % atau 3 log reduksi</p>
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<http://farmalkes.kemkes.go.id/2020/04/standar-alat-pelindung-diri-aps-dalam-manajemen-penanganan-covid-19/>

Website: <http://regalkes.kemkes.go.id/>

ALUR RELAKSASI PERCEPATAN PERIZINAN ALKES DAN PKRT PRODUK VENTILATOR DALAM NEGERI DALAM MENDUKUNG PENANGGULANGAN COVID-19



Dalam rangka percepatan penanganan Covid-19, Kemenkes melakukan upaya percepatan pemberian izin edar produk dalam negeri untuk komoditi alkes dan PKRT yang dibutuhkan melalui mekanisme One Day Service *

***ODS dihitung setelah dokumen dinyatakan lengkap**

Tarif PNBP Sertifikat Izin Edar Alat Kesehatan (Baru)	
Kelas 1.A	Rp. 1.500.000,-
Kelas 2.B	Rp. 3.000.000,-
Kelas 2.C	Rp. 3.000.000,-
Kelas 3.D	Rp. 5.000.000,-

Resusitator

Jenis Produk: Manual emergency ventilator.
 Kelas Risiko: 2.B
 Kategori: Perlatan Anestesi
 Subkategori: Perlatan Anestesi Terapeutik

Persyaratan Uji:

- Lulus uji performance/kinerja

Ventilator

Jenis Produk: Continuous Ventilator.
 Kelas Risiko: 2.C
 Kategori: Perlatan Anestesi
 Subkategori: Perlatan Anestesi Terapeutik

Persyaratan Uji:

- Lulus uji keamanan listrik (IEC 60601)
- Lulus uji performance/kinerja
- Untuk yang masif lampirkan evaluasi biokompatibilitas (bisa paralel dengan perizinan)
- Lulus uji klinik

Resusitator

Jenis Produk: Powered emergency ventilator.
 Kelas Risiko: 2.C
 Kategori: Perlatan Anestesi
 Subkategori: Perlatan Anestesi Terapeutik

Persyaratan Uji:

- Lulus uji keamanan listrik (IEC 60601)
- Lulus uji performance/kinerja
- Lulus uji klinik

Continuous Positive Airway Pressure (CPAP)

Jenis Produk: Positive Airway Pressure Delivery System.
 Kelas Risiko: 2.C
 Kategori: Perlatan Anestesi
 Subkategori: Perlatan Anestesi Terapeutik

Persyaratan Uji:

- Lulus uji keamanan listrik (IEC 60601)
- Lulus uji performance/kinerja
- Lulus uji klinik

High Flow Nasal Cannula

Jenis Produk: High flow humidified oxygen delivery device.
 Kelas Risiko: 2.B
 Kategori: Perlatan Anestesi
 Subkategori: Perlatan Anestesi Terapeutik

Persyaratan Uji:

- Lulus uji keamanan listrik (IEC 60601)
- Lulus uji performance/kinerja

Website: <http://regalkes.kemkes.go.id/>

PEDOMAN PELAYANAN PUBLIK IZIN EDAR ALAT KESEHATAN DAN PERBEKALAN KESEHATAN RUMAH TANGGA SELAMA KONDISI PANDEMI COVID 19

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

GERMAS

HELPDESK ALAT KESEHATAN DAN PKRT PRODUK PENANGANAN COVID-19

SENIN 08.00-16.00 WIB	Anita NF Rizki S	081322110754 085881409172
SELASA 08.00-16.00 WIB	Handika YP Bethalia M	08129726740 081317062217
RABU 08.00-16.00 WIB	January D Priyo Hadi P	081288301554 087878725752
KAMIS 08.00-16.00 WIB	Tri Siwi A Rachmi S	08562668319 081295892292
JUMAT 08.00-16.00 WIB	Yuanita F Nurbani L	081314474549 082124356412
SABTU 08.00-12.00 WIB	Siti Hardiyanti P	08128770988
MINGGU 08.00-12.00 WIB	Doni Maradona	082247126027

DIREKTORAT PENILAIAN DAN PERBEKALAN KESEHATAN DAN PERBEKALAN KESEHATAN KEMENTERIAN KESEHATAN 2020

DIREKTORAT PENILAIAN ALKES DAN PKRT
 DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN
 KEMENTERIAN KESEHATAN

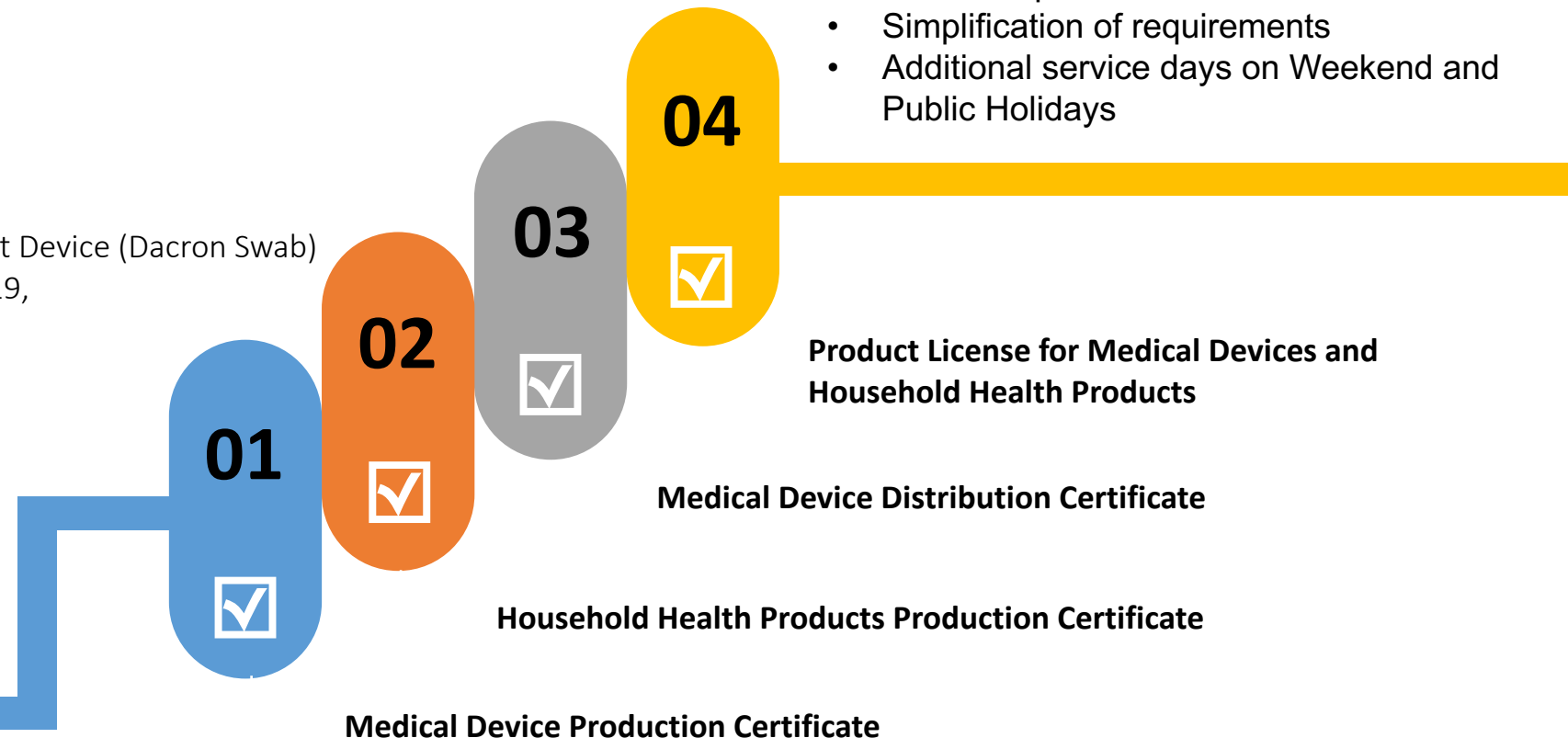
To encourage the availability of Medical Devices and Household Health Products needed in handling COVID-19

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

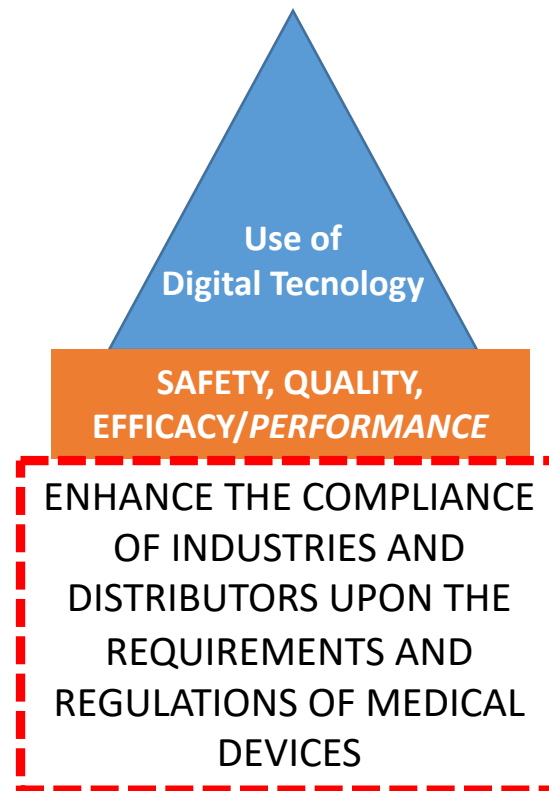


Implementation of Medical Device Control During The New Normal Era



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.

Please Visit these website to access information and guidelines

Registrasi Alat Kesehatan & PKRT Online

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA
Direktorat Jenderal Kefarmasian dan Alat Kesehatan

Registrasi Alat Kesehatan

Apikasi Registrasi Alat Kesehatan dan PKRT Online ini dibangun untuk memfasilitasi layanan publik dalam proses perizinan yang menerbitkan Izin Edar Produk Alat Kesehatan dan PKRT (Perbekalan Kesehatan Rumah Tangga). Silahkan login dengan memasukkan User ID dan Password yang Anda miliki untuk dapat mengakses fasilitas tersebut.

PERBERITAHUAN

Dalam rangka pencegahan dan untuk meminimalisir penyebaran *Coronavirus Disease (COVID-19)*, maka terhitung tanggal 17 Maret 2020 layanan konsultasi terkait permohonan registrasi izin edar alkes dan PKRT serta surat keterangan alkes dan PKRT untuk sementara dilakukan dengan konsultasi via email.

Konsultasi Alkes Kelas A dan B : subditalkonsultasi@gmail.com
 Konsultasi Alkes Kelas C dan D : subditalkes.kelascd@gmail.com
 Konsultasi Alkes IVD : subditpendrak@gmail.com
 Konsultasi Produk PKRT : seksi_pkrt@gmail.com
 Konsultasi Alkes Dalam Negeri IT Helpdesk : konsultasiprodukmandiri@gmail.com
penalkes806@gmail.com
 0813-5000-8063 (WhatsApp)

Direktorat Penilaian Alkes dan PKRT
Direktorat Jenderal Kefarmasian dan Alat Kesehatan
Kementerian Kesehatan

Login

Username

Password

Key Code

BILIA

[Login](#) [Lupa Password](#)

Berita & Pengumuman

Statistik Akses Aplikasi Bulan Februari

Link Terkait

- Pengumuman Produk yang Bukan Termasuk Perbekalan Kesehatan Rumah Tangga (PKRT)
- Pengumuman Vaccine dan Pharmaceutical (medical) Storage/Refrigerator
- Pengumuman Penggunaan Bea Meterai Rp. 10.000.-
- 22 Jawa Barat - 0,15%
- 19 Jakarta Raya - 0,13%
- 6 Jawa Timur - 0,04%
- 3 Singapore - 0,02%
- 2 Jawa Tengah - 0,01%
- 100 Tamu
- 95 Anggota yang Online saat ini
- 321 Pengunjung hari ini
- 14561 Pengunjung bulan ini
- 432508 Pengunjung dari 7 Januari 2016


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

Perizinan Sarana Produksi dan Distribusi Alat Kesehatan

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA
Direktorat Jenderal Kefarmasian dan Alat Kesehatan

Perizinan Sarana

Apikasi Perizinan Sarana Produksi dan Distribusi Alat Kesehatan Online ini dibangun untuk memfasilitasi layanan publik dalam proses perizinan yang menerbitkan Sertifikat Produksi Alkes, Sertifikat Produksi Perbekalan Kesehatan Rumah Tangga (PKRT), dan Sertifikat Distribusi Alat Kesehatan. Silahkan login dengan memasukkan User ID dan Password yang Anda miliki untuk dapat mengakses fasilitas tersebut.



Login

Username

Password

Key Code

BENGKULU

Sertifikat Terbit

- FK.01.01/VI/4587-a/2021 - PT. DIAN MAHARANI MEDIKA
- FK.01.01/VI/4585-a/2021 - PT. MITRA PESONA SAMUDRA
- FK.01.01/VI/4593-a/2021 - PT. ROSE MEGAH MANDIRI
- FK.01.01/VI/4588-a/2021 - PT. SEMESTA MUDA BERKARYA
- FK.01.01/VI/4592-a/2021 - PT. ABBOTT PRODUCTS INDONESIA
- FK.01.01/VI/4586-a/2021 - PT. WICKASANA OVERSEAS INTERNATIONAL TBK

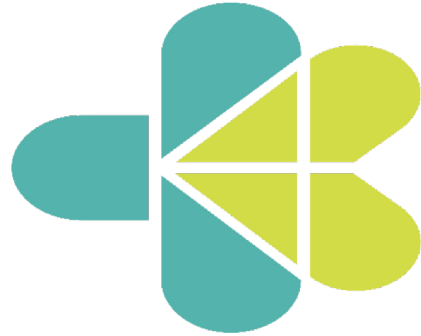
Daftar Pencabutan Produsen & Penyalur

- PT. RAMBBO FARMASI JAYA - HK.02.06.Aikes/IV/285/AK.2/2015
- PT. TIONE INDONESIA, JAYA - FK.01.01/VI/1015-a/2019

Berita & Pengumuman

- Permohonan Sertifikasi CPAKB, CPPKRTB dan CDAKB Melalui Sistem Online
- PENGUMUMAN PERUBAHAN JADWAL KONSULTASI LOKET 5 ULT
- Pengumuman Penggunaan Bea Meterai Rp. 10.000.-
- Pedoman Pelayanan Publik Sertifikat Produksi dan Surat Komitmen Sertifikat Produksi Alkes/PKRT dan Distribusi Alkes
- Brosur Layanan Perizinan Percepatan Covid-19
- TEMPLATE LAPORAN KESIAPAN PERUSAHAAN SARANA PRODUKSI DAN/ATAU DISTRIBUSI ALKES DAN/ATAU PKRT

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



**KEMENTERIAN
KESEHATAN
REPUBLIK
INDONESIA**

TERIMA KASIH

THANK YOU



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

2021