INDONESIAN MEDICAL DEVICES REGULATION

Directorate of Medical Device Production and Distribution Service
MINISTRY OF HEALTH REPUBLIC OF INDONESIA

Indonesia has been regulating Medical Device since 1991

ensure the safety, quality, performance/efficacy, affordable and appropriateness

to **avoid risk** of medical devices, to **reduce cost** of public health care

“patient safety”

E-System For Medical Device in Indonesia

E- Production License

E- Catalog

E- Distributors License

E- Planning

E- Info Alkes

E- Registration

E- Watch Alkes

e- INSW

E- Report

INDONESIA MEDICAL DEVICE REGULATIONS

Director General for Pharmaceutical and Medical Device Services (Dra. Maura Linda Sitanggang , Apt., Ph.D)

Director for Medical Devices Production and Distribution Service (Drg. Arianti Anaya, MKM)

- **Head of Sub Directorate For Medical Devices**
  - **Head of Section for Electromedic Medical Device**
  - **Head of Section for Non Elek Medical Device**
- **Head of Sub Directorate For IV D & House hold**
  - **Head of Section for IV D**
  - **Head of Section for House Hold**
- **Head of Sub Directorate For INSPECTION**
  - **Head of Section for Production & Distribution Facility**
  - **Head of Section for Med Device & House hold Product**
- **Head of Sub Directorate for STANDARD And Certification**
  - **Head of Section for Med Device Standard**
  - **Head of Section for Production And Distribution Certification**

INDONESIA MEDICAL DEVICE REGULATION SYSTEM

Pre-Market Control

- Manufacturer License
- **Distribution License**
- **Registration License**

→ ISO 13485 for QMS

→ Good Distribution Practice

→ ASEAN CDST

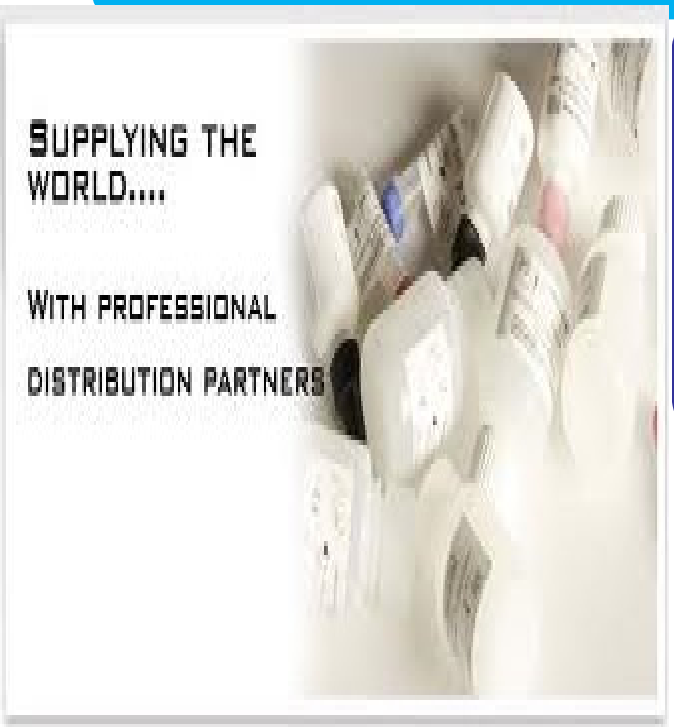
Post-Market Control

- Sampling
- Monitoring
- Vigilance
- Advertising

→ ASEAN AMDD Guideline on Post market control

DISTRIBUTION OF MEDICAL DEVICE REGULATION

Who can distribute Medical Device in Indonesia ??



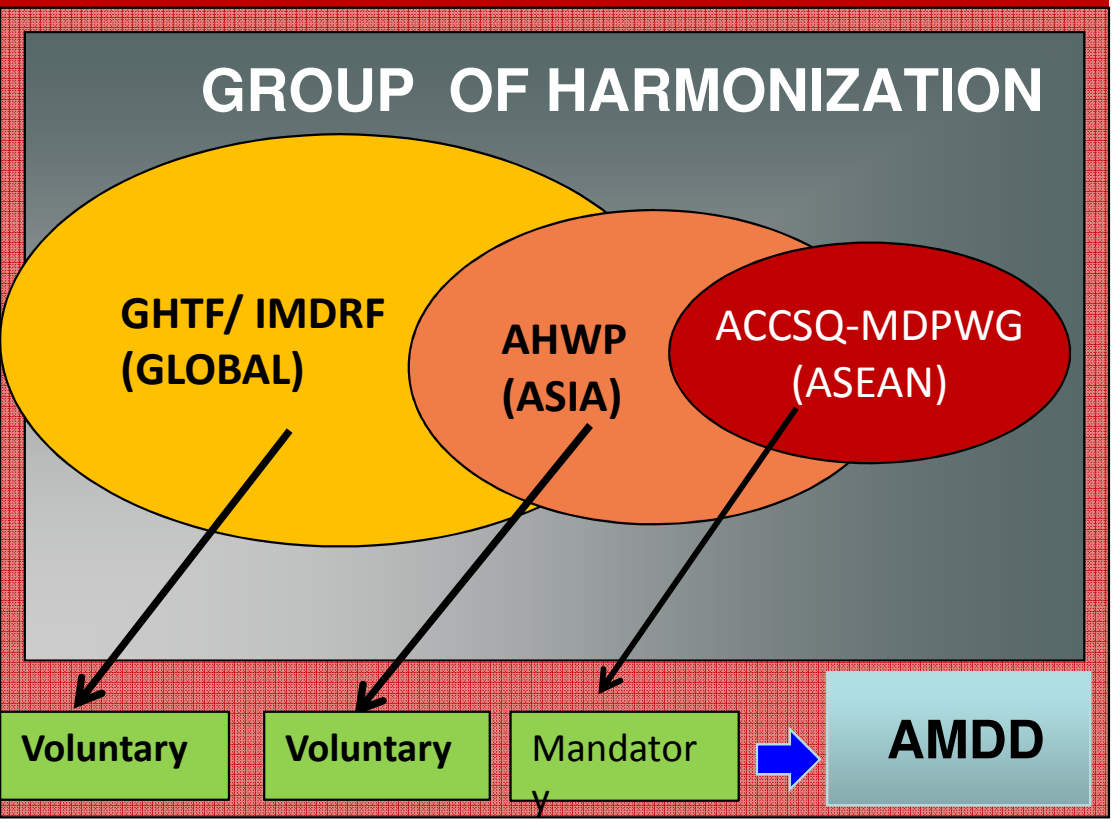
* Company that have Distribution license (IPAK) issued by MOH RI
* Import Products must have only one legal importir and distributor in Indonesia

DISTRIBUTOR

Good Distribution Practice

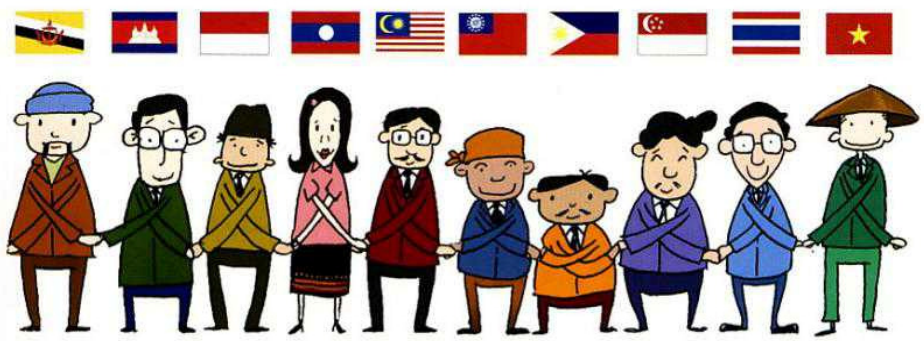
Periodic Audit to assess compliance all Distributors by MOH RI

HARMONIZATION OF MEDICAL DEVICES REGULATION



ACCSQ-MDPWG ACHIVEMENT

ASEAN HARMONIZATION



1.(CSDT) Common Submission Dossier Template

2. Quality System ISO 13485

3. ASEAN Post Market Surveillance

4. ASEAN Alert System

5. ASEAN Medical Devices Directive (AMDD)

PREMARKET CONTROL

AMDD Has Been Signed on 21st of November 2014AMDD is subject to be ratified by ASEAN Member States. AMDD becomes effective when ASEAN Member States deposit instruments of ratification with ASEAN Secretariat General

INDONESIA has been adopted

1. Common Submission Dossier Template CSDT
2. ISO 13485 for Quality Management System
3. Good Distribution Practice
4. Post market Surveillance System
5. International Standard and Indonesia National Standard for ensuring the safety, quality and effectiveness of medical device

Mandatory

ASEAN HARMONISATION REGULATION SYSTEM PRESENT AS AMDD (ASEAN MEDICAL DEVICE DIRECTIVE)

MEDICAL DEVICE DEFINITION
INDONESIA MOH Decree – 1190/2010

Medical devices are instruments, apparatuses, machines and/or implants that do not contain medicines used to prevent, diagnose, cure and relieve diseases, treat sick people, recover human health and/or form structures and correct the body function. Based on the objective of use as meant by the producer, medical devices may be used individually or in combination for human beings with one or several purposes as follows:

a.diagnosis, prevention, monitoring, treatment or reduction of diseases;
b.diagnosis, monitoring, treatment, reduction or compensation of sick condition;
c.investigation, replacement, modification, anatomical support, or physiological process;
d.support or maintain life;
e.obstruct fertilization;
f.disinfectant of medical devices;
g.provide information for medical or diagnosis purposes through the *in vitro* test on the specimen and human body

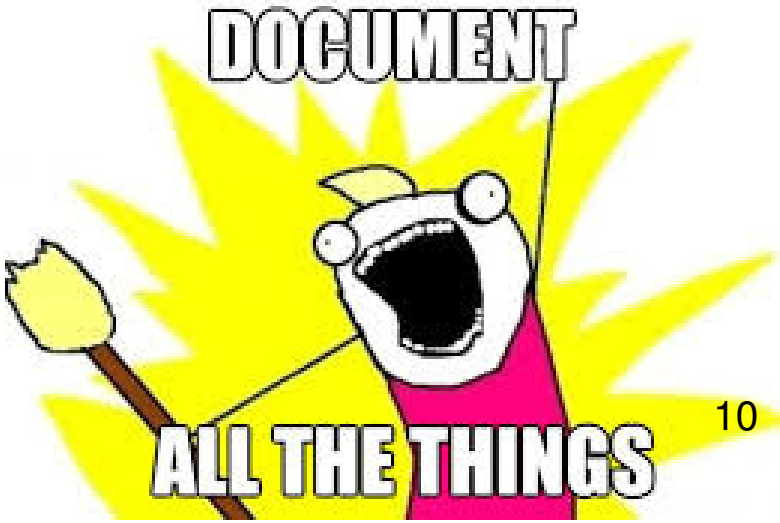
CLASSIFICATION SYSTEM FOR MEDICAL DEVICE BASED ON AMDD (ASEAN MEDICAL DEVICE DIRECTIVE)

Class	Risk Level	Examples
A	Low risk	Cholesterol, uric acid test system; Surgical Instrument; Bandage, Surgical camera; Electric operating table, Patient scale
B	Low-Moderate risk	Pregnancy self testing, Electric Hospital Bed, Surgical Lamp, Surgical Mask
C	Moderate-High risk	Blood glucose self testing, ECG, Xray Unit, Syringe, Condom, Contact lens
D	High risk	HIV Blood donor screening, Stent, Intra ocular lens (IOL), Defibrillator, Pacemaker

MAIN SECTIONS OF THE CSDT

EXECUTIVE SUMMARY

ELEMENTS OF THE COMMON SUBMISSION DOSSIER TEMPLATE



EXECUTIVE SUMMARY

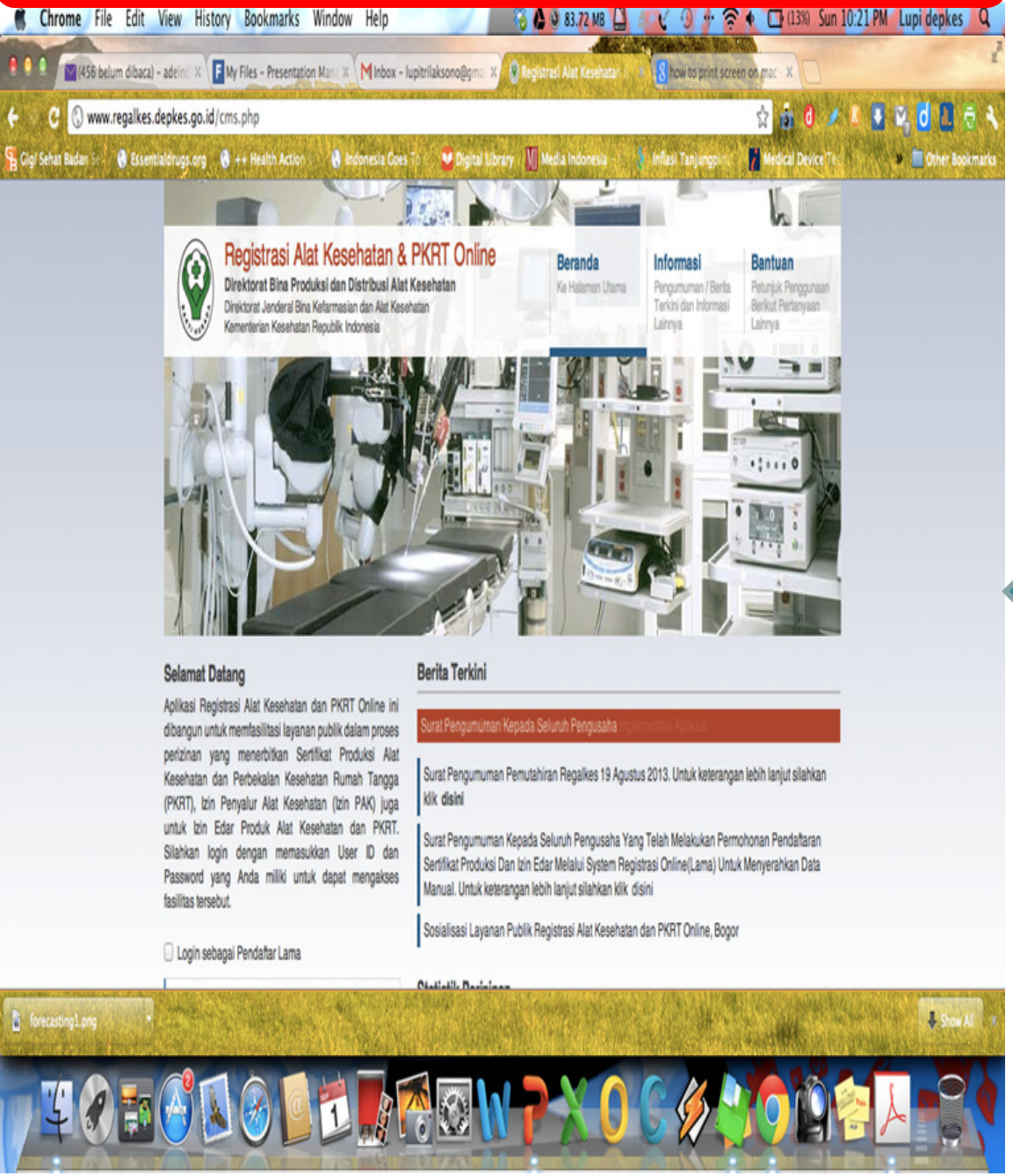
- Overview
- Commercial marketing history
- Intended uses and indications
- Regulatory approval or marketing clearance obtained
- Status of pending regulatory approval
- Important safety or performance information

ELEMENTS OF THE COMMON SUBMISSION DOSSIER TEMPLATE

- RELEVANT ESSENTIAL PRINCIPLES AND METHOD USED TO DEMONSTRATE CONFORMITY
- DEVICE DESCRIPTION
- SUMMARY OF DESIGN VERIFICATION AND VALIDATION DOCUMENTS
- DEVICE LABELING
- RISK ANALYSIS
- MANUFACTURER INFORMATION

E-REGISTRATION FOR MEDICAL DEVICE INDONESIA

http://www.regalkes.depkes.go.id



Back Ground of e-Registration On line

- Wide area of Indonesia teritory
- Optimize public service
- Quick registration system
- can be acess anywhere and everywhere for further information

INDONESIA MEDICAL DEVICE PRODUCT CLASIFICATION

Currently Medical Device products classification in Indonesia

Class	Risk Level	Level of Control	Administration Fee
I	Low risk	General control	1.500.000
II	Moderate risk	Special control	3.000.000
III	High risk	Pre market approval	5.000.000

Based on the level of control necessary to provide reasonable assurance of its safety and effectiveness

REGISTRATION PROCEDURE

Applicant

Expert Team

On-Line Registration

Approval Administration Payment

Documents Evaluation

yes

Final Decision

No

Registration Number

NATIONAL SINGLE WINDOW
Coordination with Indonesian Customs

SERVICE AGREEMENT FOR MEDICAL DEVICE PRODUCT

Started from Official payment received with condition the document is complete

Class I : 45 days
Class II : 90 days
Class III : 120 days

Extended time if Additional document required

Registration Number Certificate as Marketing License in Indonesia

Requirement For Medical Device Class I

- Production License for Manufacturer
- Distribution License for distributor
- Letter of authorization with minimum 2 years term agreement Legalized by the Indonesian Embassy (KBRI)
- ISO 13485 Certificate
- Free of Sale Certificate issued by MOH or competent authority

ADMINISTRATIF DOCUMENTS

Technical Documents

- Formulation/raw material components and their function
- Product specifications
- Procedure, data and result of stability test
- IEC 61010-1:2001 (for IVD instrument product)
- IEC 60601-1:2001 (for electric medical device)
- Sterilization validation process (Sterile products)

Requirement For Medical Device Class II

- Requirement Medical Device Class I

- ❑ Certificate of analysis finished product
- ❑ Performance/functional test / efficacy test (Electric products)
- ❑ Performance/Characteristic Evaluation (IVD Product)
- ❑ Production flowchart

Requirement For Medical Device Class III

- Requirement Medical Device Class II

- ❑ Risk management according to ISO 14971:2007
- ❑ COA Raw material
- ❑ Clinical studies/evaluation data
- ❑ Biocompatibility test
- ❑ Published Journal
- ❑ Post market evaluation procedure

Label, IFU, Brochure/Leaflet and Manual Book of Medical Device

- Labeling of the product packaging :
  - Enclosed the figure,
  - Product name,
  - Manufacture name & address ,
  - Registration no,
  - Batch No /Lot No,
  - Warning with Symbol/logo, Indonesian or English language

- Manual book and IFU should be provide in original languange and Indonesian language
- Brochure/leaflet with Indonesian and/or English language

SPECIAL REQUIREMENT PRODUCTS

1. HIV Products	Should be tested at the Indonesia Reference National Laboratory Hospital (RSCM)
2. Menstrual Pads and Adult Diappers, Condom, syringe	Should have fluorosence tested at the Indonesia National Laboratory (Sucofindo, The Food and Drug Monitoring Agency/BPOM)
3. For the product contain animal origin as its raw material (ex: catgut)	Should have certificate of free Disease form the product country of origin
4. For the product contain radiation (ex: Xray unit)	Should have safety radiation certificate from National Nuclear Agency (BAPETEN)
5. Open Software	Software Validation report From Manufacture or independen laboratotium

REGISTRATION IMPORT MEDICAL DEVICE LICENSE

- Validity of registration number: Minimum 2 Years and Maximum 5 years
- All medical device must get registration number before entering the Indonesia territory.
- Spare part and accessories, is not required to be registered
- All accessories of the product will attached in registration number in order to simplify the custom release

MINISTRY OF HEALTH OF THE REPUBLIC OF INDONESIA
DIRECTORATE GENERAL OF PHARMACEUTICAL AND MEDICAL DEVICES DEVELOPMENT
Jl. H. R. Rasuna Said Blok X5 Kavling No. 4-9 Jakarta 12950
Phone: +6221-5201590 (Hunting) Facsimile: +6221-52964838 Po BOX 203

In accordance with:

The Regulation of The Minister Health Of The Republic Of Indonesia No. 1190/Menkes/Per/VIII/2010 dated August 23, 2010 regarding Medical Devices and Household Products Registration License

Hereby given the marketing licence under:

NUMBER OF REGISTRATION LICENSE
MEDICAL DEVICE

KEMENKES RI AKL 20502214455

Name of Product	:	**ROHTO Neo Eye Foldable Lens**
Generic Name	:	Intraocular Lens
HS Code	:	9022.14.00.00
Category	:	Eye Device
Sub Category	:	Prosthetic Eye Device
Type/Size	:	RF-22L/ Dioptre +4 s/d +40
Packaging	:	Box Containing Lens Holder @ 1 Lens
Name of Manufacturer	:	PT. ROHTO LABORATORIES INDONESIA, PADALARANG
Name of Distributor	:	PT. ROHTO LABORATORIES INDONESIA, PADALARANG
Under License from	:	-
Stipulation	:	1. This registration license is valid within …… 2. Submit the periodical report every 1 (one) year concerning type and side effect of the marketing products is an obligation
Rules and Regulations	:	1. if on the other day there is another party who has a right upon the above agency appropriate with the valid regulation, the agency should be willing to release of the distributor authorization for the product. 2. if on the other day there is any fault, this license will be reviewed.

Jakarta, ……., 20….

On behalf of Director General,
Director for
Medical Device Production and Distribution Development,

SAMPLE

Dra. Nasirah Bahaudin, Apt., MM
NIP. 19531031 198501 2 001

INDONESIA NASIONAL SINGLE WINDOW

MINISTRY OF HEALTH

1. Registration number
2. Name of Product
3. Generic Name of Product
4. Type/ size
5. Name & Address Manufacture
6. Name & Address Distributor
7. Tax Number
8. HS Code Number
9. Release date
10. Expired date
11. Country of origin

INSW
CONSISTENCY | TRANSPARENCY | SIMPLICITY | EFFICIENCY

Portal
Indonesia NSW

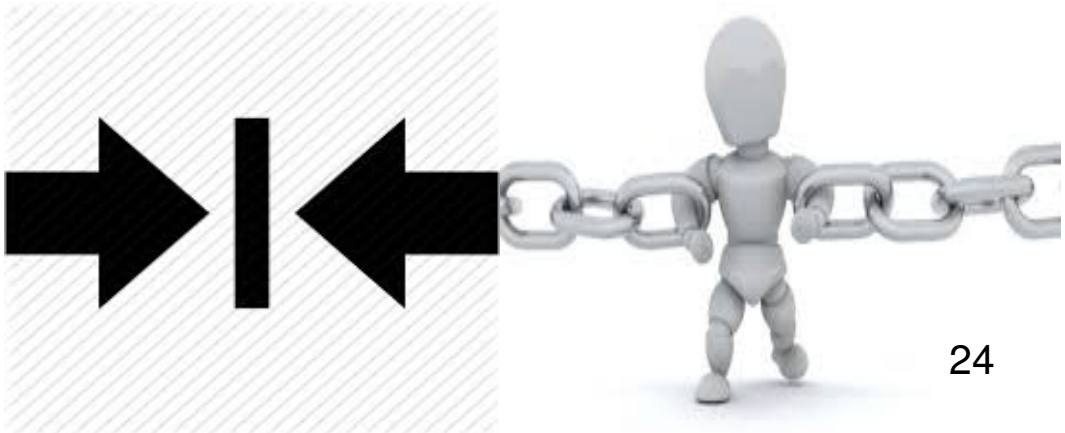
Customs

Bea Cukai

Release

General Constraints Faced Of Medical Device Registration Thus Application Rejected

- Uncomplete Document Requirement, for Examples :
  - IEC 61010, 60601 and/or test report
  - Clinical studies/evaluation
  - Certificate of analysis finished product
  - Uncomplete labeling
- Unwell understand about regonline application
- Missing new update information, regulation and procedure
- Expiration Document



- Indonesia is highly concern about the medical device safety, quality and efficacy which are entering Indonesia market.

- To filter the substandard Medical device, Indonesia Medical Device Regulation always inline with global, asia, and ASEAN level.
- Harmonization of medical device need to be done throughout the regional and global to protect public health and ensure public safety.

THANK YOU

TERIMA KASIH

BAKTI HUSADA

Pulau Komodo