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”
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

GROUP OF HARMONIZATION

GHTF/IMDRF (GLOBAL)  
AHWP (ASIA)  
ACCSQ-MDPWG (ASEAN)

Voluntary  
Voluntary  
Mandatory  
AMDD

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)
AMDD Has Been Signed on 21st of November 2014. AMDD 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
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.
<table>
<thead>
<tr>
<th>Class</th>
<th>Risk Level</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Low risk</td>
<td>Cholesterol, uric acid test system; Surgical Instrument; Bandage, Surgical camera; Electric operating table, Patient scale</td>
</tr>
<tr>
<td>B</td>
<td>Low-Moderate risk</td>
<td>Pregnancy self testing, Electric Hospital Bed, Surgical Lamp, Surgical Mask</td>
</tr>
<tr>
<td>C</td>
<td>Moderate-High risk</td>
<td>Blood glucose self testing, ECG, Xray Unit, Syringe, Condom, Contact lens</td>
</tr>
<tr>
<td>D</td>
<td>High risk</td>
<td>HIV Blood donor screening, Stent, Intra ocular lens (IOL), Defibrillator, Pacemaker</td>
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MAIN SECTIONS OF THE CSDT

EXECUTIVE SUMMARY

ELEMENTS OF THE COMMON SUBMISSION DOSSIER TEMPLATE

User manual
Specification
SW Design
Electronics
Compliance
Test Plan
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
ELEME NTS 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 territory
• Optimize public service
• Quick registration system
• can be access anywhere and everywhere for further information
Currently Medical Device products classification in Indonesia

<table>
<thead>
<tr>
<th>Class</th>
<th>Risk Level</th>
<th>Level of Control</th>
<th>Administration Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Low risk</td>
<td>General control</td>
<td>1.500.000</td>
</tr>
<tr>
<td>II</td>
<td>Moderate risk</td>
<td>Special control</td>
<td>3.000.000</td>
</tr>
<tr>
<td>III</td>
<td>High risk</td>
<td>Pre market approval</td>
<td>5.000.000</td>
</tr>
</tbody>
</table>

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

Applicant

On-Line Registration

Approval Administration Payment

Documents Evaluation

Expert Team

Final Decision

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

- 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)

Technical Documents
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 language and Indonesian language

- Brochure/leaflet with Indonesian and/or English language
1. HIV Products

Should be tested at the Indonesia Reference National Laboratory Hospital (RSCM)

2. Menstrual Pads and Adult Diapers, 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
• 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
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
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 concerned 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

Pulau Komodo