KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

GERMAS
Gerakan Masyarakat Hidup Sehat

GHWP Global Harmonization Working Party
Towards Medical Device Harmonization

INDONESIA

Medical Devices Regulation

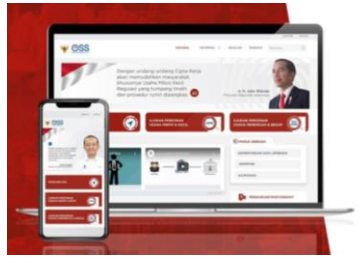
By **ISMIYATI SURATA**
Senior Health Administrator
Team Work Coordinator for Certification and Inspection of Production Facility
Directorate of Medical Devices Post Market Control
Ministry of Health

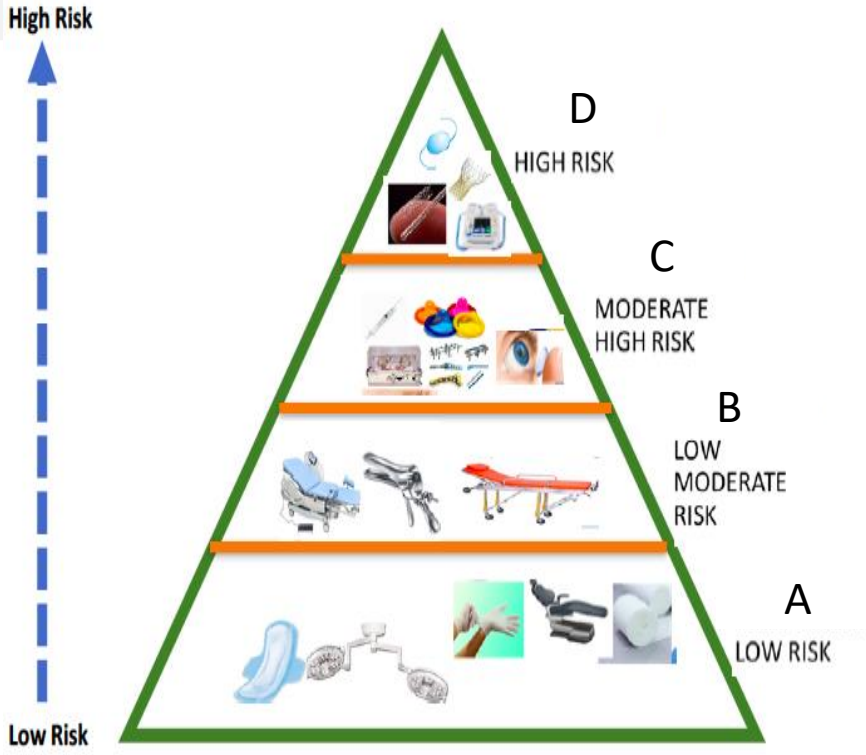
BerAKHLAK
Berorientasi Pelayanan Akuntabel Kompeten Harmonis Loyal Adaptif Kolaboratif

#bangga melayani bangsa

27th GHWP Annual Meeting and 27th GHWP TC Meeting, 27th – 30th Nov 2023
Shanghai International Convention Center

Medical Device Registration and Classification





AMDD Rule

Https://regalkes.kemkes.go.id

Directorate for Production and Distribution of Medical Devices

- ✓ All class of medical devices must be registered at MoH before distribute in Indonesia
- ✓ Registration process is carried out via national single system for licencing all business purposes at Indonesia that called Online Single Submission (OSS – Https://oss.go.id) that is integrated with MoH online system
- ✓ Validity period of marketing licence is in accordance to the term of the appointment letter from principal, maximum of 5 years

MoH Regulation No. 62 Year 2017 regarding Marketing Licence of Medical Device and Household Health Product

MoH Regulation No.14 Year 2021 regarding Standards for business activities and products in risk-based business licensing in the health sector

Simplification and acceleration process for certain medical devices (Class A) since Januari 2022 ➔ notification route

List of Medical Devices
(Notification Route)

1 Arm sling

2 Body waste receptacle

3 Cane

4 Cane, crutch, and walker tips and pads.

5 Cold pack.

6 Crutch

7 Dental floss

8 Elastic bandage

9 Flotation cushion

10 Hernia support

11 Hot or cold disposable pack

12 Hot/cold water bottle

13 Ice bag

14 Limb orthosis

15 Manual breast pump

16 Manual toothbrush

17 Mechanical wheelchair

18 Mechanical walker

19 Medical adhesive tape and adhesive bandage (NON STERILE)

20 Medical disposable bedding

21 Medical insole

22 Moist heat pack.

23 Nipple shield

24 Nonresorbable gauze/sponge for external use (NON STERILE)

25 Ophthalmic eye shield

26 OTC Denture cleanser

27 Patient scale

28 Protective garment for incontinence.

29 Scented or scented deodorized menstrual pad

30 Stand-on patient scale

31 Teething ring

32 Therapeutic massager

33 Truncal orthosis

34 Unscented menstrual pad

Product Registration Timeline & Fees

Risk Class	Local	Imported	Notification	Fees
Class A	10 days	15 days	7 days	IDR 1,500,000
Class B	20 days	30 days	-	IDR 3,000,000
Class C	20 days	30 days	-	IDR 3,000,000
Class D	30 days	45 days	-	IDR 5,000,000

Indonesia implemented Good Registration Management for the process ➔ Good Review Practice and Good Submission Practice

After submit the registration, applicant only has 1 time opportunity to give additional data within 10 days (class A, B, and C) and 15 days (class D) after got feedback from the evaluator team

The product registration process is conducted by MoH

Directorate for Production and Distribution of Medical Devices

Product Registration Requirements →AMDD

FORM A. ADMINISTRATIVE DATA

1. Business Licence (NIB)
2. Medical Device Distributor License issued by MoH which is still valid (for local and import product distributor)
3. Power of Attorney (Letter of Authorization) as sole agent or sole distributor which authorize to register the medical device from the principal/factory of origin and have to legalize by the local Indonesian Embassy (KBRI)
4. Certificate of Free Sale (CFS) from Regulatory Authority
5. Certification and document mentioning conformity standard of product, requirement of safety, effectiveness, and quality system in design and manufacturing process (ISO 9001, ISO 13485, CE Certificate), CPAKB
6. Executive Summary contains of information about marketing history, mechanism of the product, indication, formula, and history of product usage
7. Standard and declaration of conformity against the standard on the production/manufacturing of medical device
8. Patent certificate/ Brand name registration letter and Declaration of no objection to release the brand name/ Declaration of no objection to release the agency
9. Statement Letter of truth and accurate document

FORM B. PRODUCT INFORMATION

1. Explanation
2. Description and feature of Medical Device
3. Intended Use
4. Indication
5. Instruction for use
6. Contra indication (if any)
7. Warning(if any)
8. Caution (jif any)
9. Potential Adverse event (if any)
10. Alternative therapy (if any)
11. Material
12. Manufacturer Information (if any)
13. Production Process

FORM C. SPECIFICATION & QUALITY ASSURANCE

1. Functional characteristics and specification of the medical device technical performance.
2. Additional information of device characteristics which are not yet included in the previous part.
3. Summary of design verification and document validation
4. Pre Clinical studies
5. Test result of software validation (if applicable).
6. Result of the research on any device containing biologic material.
7. Clinical Evidence and Clinical Evaluation
8. Risk Analysis
9. Result of Risk Analysis
10. Specification and/or requirement of raw material
11. Specification of packaging (Diagnostic product)
12. Provide data of analysis result and or clinical test (specificity, sensitivity and stability) for reagent or in-vitro diagnostic product
13. Provide analysis test result/clinical test result and device safety

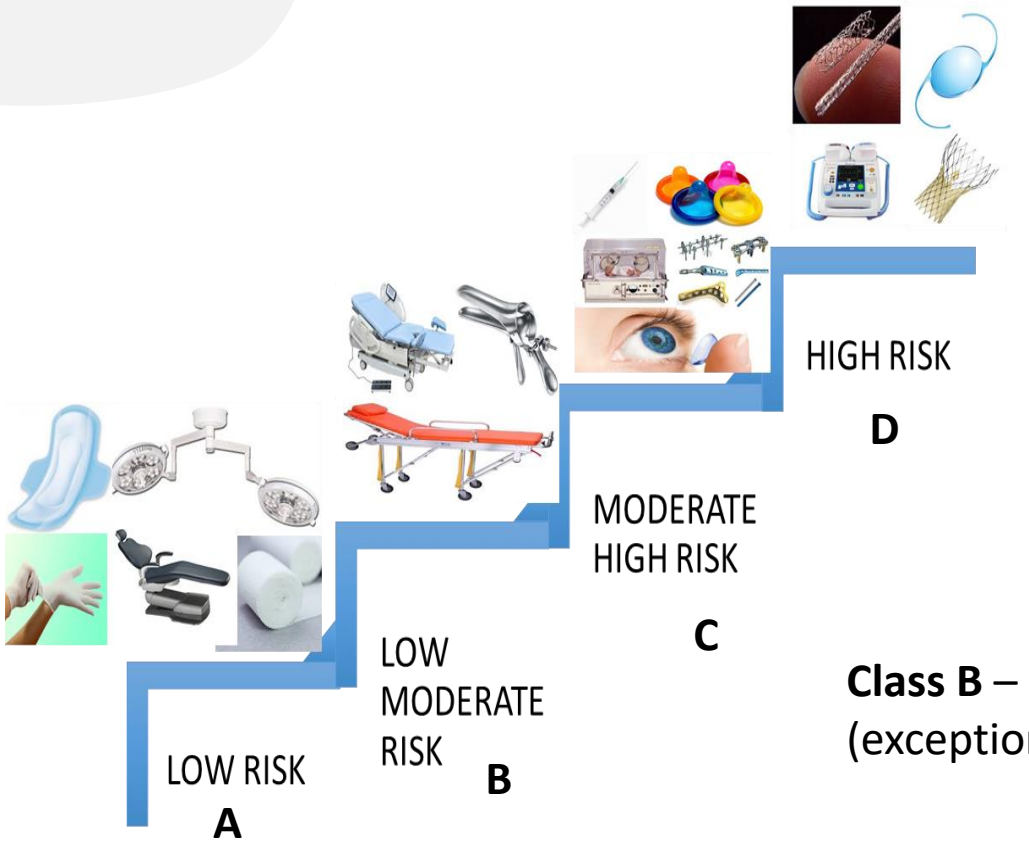
FORM D. INSTRUCTION FOR USE

1. Labelling Artwork
2. Explanation on symbols are used in packaging and labeling
3. Instruction for use, raining material & guidance of installation and its maintenance
4. *Lot numbering System*
5. List of accesories (if any)

FORM E. POST MARKET EVALUATION

1. SOP for product complaint handling, recall, vigillance, etc

Product Registration Requirements



Class D – Complete all form A, B, C, D, and E

Class C – Complete Form A, B, D, and E. Form C (exception C4, C7, C8, and C9

Class B – Complete Form B, D and E. Form A (exception A6). Form C (exception C4, C7, C8, C9 and C10).

Class A – Complete Form B, D and E. Form A (exception A6). Form C (exception C4, C7, C8, C9 and C10).

Quality Management System

Medical Devices Industry

- Mandatory to implement Good Manufacturing Practice MD Guidance, which develop by MOH adopted from ISO 13485:2016
- A technical responsible person who already has GMP-MD training certificate
- MoH Regulation No. 20 Year 2017 regarding GMP-MD Guidance
- MoH Regulation No. 14 Year 2021

Medical Devices Distributor

- Mandatory to implement Good Distribution Practice MD Guidance
- A technical responsible person who already has GDP-MD training certificate
- MoH Regulation No. 4 Year 2014 regarding GDP-MD Guidance
- MoH Regulation No. 14 Year 2021

The certification process (including audit) is conducted by MoH

Https://sertifikasialkes.kemkes.go.id

Directorate for Medical Device Post Market Control

STRENGTHENING POST MARKET CONTROL

Product Sampling & Testing

- ✓ Routine done by MoH
- ✓ On September 2023, MoH released anouncement that marketing licence holder of certain medical devices require post market testing and reported to MoH every 2 years

Post Market Surveillance

Marketing licence holder required to report any adverse events and product recall

Facility Inspection

Routine inspection at production and distribution facility to ensure the compliance with standards and regulation

Advertising Control

MoH Regulation No. 76 year 2017 regarding Advertising of Medical Devices and Household Health Products

Reporting System

E-report

National Reporting System of MD Production and Distribution, mandatory to report every 6 months

E-watch

National Reporting System of MD Adverse Events – synchronized with hospital information system, currently integrate with patient safety reporting

Mobile Alkes

A mobile application to search for product information, marketing licence number, companies and also make reports/complaints regarding Medical Devices and household health products

List of Medical Devices
(Post market in country testing)

Group of Product	Type of Product	Type of Testing
Sterile Non electromedical device	All sterile products	Sterility test
	Sterile Gauze	Sterility test & Fluorescence test
Sterile Non electromedical Products with needle	Disposable syringe, IV Cannula, IV Catheter, Wing needle, Fistula Needle, Infusion set with needle,	Sterility test & needle sharpness test
Electromedical device	USG, Continuous Ventilator, Infusion Pump, Syringe Pump	Electrical safety and performance test
Non Sterile Non electromedical device	Condom	Burst test, leak test
Diagnostic in Vitro	Rapid Diagnostic Test (HIV, Syphilis, Hepatitis, and Dengue)	Sensitivity Test, Specificity Test

Xie Xie

Terima Kasih

Thank You

farmalkes.kemkes.go.id farmalkes @farmalkes @farmalkes farmalkesTV

About Speaker

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Working Experience at MoH

2006 – 2012 Reviewer of Medical Devices – Directorate of Production and Distribution of Medical Devices

2012 – 2015 Head of Section of Medical Devices Product Standardization - Directorate of Production and Distribution of Medical Devices

2016 – 2018 Head of Section of Domestic Medical Devices Product – Directorate of Medical Devices Evaluation

2019 – 2020 Head of Section for Certification, Directorate of Medical Devices Post Market Control

2020 – 2021 Coordinator for Standardization and Certification, Directorate of Medical Devices Post Market Control

2022 – now Senior Health Administrator, Team Work Coordinator For Certification And Inspection of Production Facility, Directorate of Medical Devices Post Market Control