

REGULATION OF THE MINISTER OF HEALTH

OF THE REPUBLIC OF INDONESIA

NUMBER 62 OF 2017

ON

PRODUCT LICENSE OF MEDICAL DEVICES, IN VITRO DIAGNOSTIC MEDICAL
DEVICES AND HOUSEHOLD HEALTH PRODUCTS

BY THE BLESSINGS OF ALMIGHTY GOD

MINISTER OF HEALTH OF THE REPUBLIC OF INDONESIA,

- Considering :
- a. that in order to ensure Medical Devices, In Vitro Diagnostic Medical Devices and Household Health Products that comply with the standard and/or requirements of safety, quality, and efficacy/performance to protect the public, a regulation on product license will be required;
 - b. that Regulation of the Minister of Health Number 1190/MENKES/PER/VIII/2010 on Product License of Medical Devices and Household Health Products, it is necessary to align with the development of the regulation harmonization at ASEAN and at global levels and with legal needs;
 - c. that based on considerations as referred to in point a and point b, it is necessary to issue Regulation of the Minister of Health on Product License of Medical Devices, In Vitro Diagnostic Medical Devices and Household Health Products;

- Observing : 1. Law Number 8 of 1999 on Consumer Protection (State Gazette of the Republic of Indonesia of 1999 Number 42, Supplement to the State Gazette of the Republic of Indonesia Number 3821);
2. Law Number 36 of 2009 on Health (State Gazette of the Republic of Indonesia of 2009 Number 144, Supplement to the State Gazette of the Republic of Indonesia Number 5063);
3. Law Number 23 of 2014 on Local Government (State Gazette of the Republic of Indonesia of 2014 Number 244, Supplement to the State Gazette of the Republic of Indonesia Number 5587) as several times amended, and last by the Law Number 9 of 2015 on Second Amendment to Law Number 23 of 2014 on Local Government (State Gazette of the Republic of Indonesia of 2015 Number 58, Supplement to the State Gazette of the Republic of Indonesia Number 5679);
4. Government Regulation Number 72 of 1998 on Security to Pharmaceutical Preparation and Medical Devices (State Gazette of the Republic of Indonesia of 1998 Number 138, Supplement to the State Gazette of the Republic of Indonesia Number 3781);
5. Government Regulation Number 21 of 2013 on Type and Tariff of Non-Tax State Revenue applicable in the Ministry of Health (State Gazette of the Republic of Indonesia of 2013 Number 56, Supplement to the State Gazette of the Republic of Indonesia Number 5408);
6. Presidential Regulation Number 35 of 2015 on Ministry of Health (State Gazette of the Republic of Indonesia of 2015 Number 59);
7. Regulation of the Minister of Health Number 1189/MENKES/PER/VIII/2010 on Medical Device Production and Household Health Products (State Bulletin of the Republic of Indonesia of 2010 Number 399);
8. Regulation of the Minister of Health Number 1191/MENKES/PER/VIII/2010 on Medical Devices

- Distribution (State Bulletin of the Republic of Indonesia of 2010 Number 401);
9. Regulation of the Minister of Health Number 76 of 2013 on Advertising of Medical Devices and Household Health Products (State Bulletin of the Republic of Indonesia of 2014 Number 192);
 10. Regulation of the Minister of Health Number 70 of 2014 on Company engaged in Medical Devices and Household Health Products (State Bulletin of the Republic of Indonesia of 2014 Number 1563);
 11. Regulation of the Minister of Health Number 64 of 2015 on Organization and Work Procedures of Ministry of Health (State Bulletin of the Republic of Indonesia of 2015 Number 1508);
 12. Regulation of the Minister of Finance Number 32/PMK.05/2014 on State Revenue under Electronic System (State Bulletin of the Republic of Indonesia of 2014 Number 200);
 13. Regulation of Minister of Agriculture Number 107/Permentan/SR.140/9/2014 on Pesticide Control (State Bulletin of the Republic of Indonesia of 2014 Number 1274);
 14. Regulation of the Minister of Agriculture Number 39/Permentan/SR.330/7/2015 Pesticide Registration (State Bulletin of the Republic of Indonesia of 2015 Number 1047);

HAS DECIDED:

To issue : REGULATION OF THE MINISTER OF HEALTH ON PRODUCT LICENSE FOR MEDICAL DEVICES, IN VITRO DIAGNOSTIC MEDICAL DEVICES AND HOUSEHOLD HEALTH PRODUCTS.

CHAPTER I
GENERAL PROVISIONS

Article 1

In this Ministerial Regulation:

1. Product License means an authorization for Medical Devices, In Vitro Diagnostic Medical Devices and Household Health Products produced by Producer, and/or imported by Medical Devices Distributor or importer that will be distributed within the territory of the Republic of Indonesia, based on evaluation on safety, quality, and efficacy/performance.
2. Medical Devices means any instruments, apparatus, machines and/or implants that do not contain drugs used to prevent, diagnose, cure and relieve any diseases, treat sick person, recover human health, and/or form the structure of, and improve, body functions.
3. In Vitro Diagnostic Medical Devices means any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination with any other reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, that are intended by its product owner to be used in vitro for the examination of any specimen, including any blood or tissue donation, derived from the human body, solely or principally for the purpose of providing information concerning a physiological or pathological state or a congenital abnormality; to determine the safety and compatibility of any blood or tissue donation with a potential recipient, or to monitor therapeutic measures and includes a specimen receptacle.
4. Household Health Products (*Perbekalan Kesehatan Rumah Tangga*), hereinafter abbreviated to PKRT, means any devices, materials, or mixed materials to maintain and take care of, human health, intended for household use and public facilities.

5. Production Certificate means a certificate to produce Medical Devices, In Vitro Diagnostic Medical Devices and PKRT.
6. Production means any activity to make, process, package, and/or assemble in order to produce Medical Devices, In Vitro Diagnostic Medical Devices and PKRT.
7. Producer means any company formed as business entity that owns Production Certificate to produce including to assemble and/or repackage the Medical Devices, In Vitro Diagnostic Medical Devices and PKRT domestically.
8. Manufacturer means any overseas company that manufactures Medical Devices, In Vitro Diagnostic Medical Devices and PKRT that have complied with quality management system.
9. Principal means any Manufacturer or overseas representative appointed and authorized by the Manufacturer or Product Owner to appoint Medical Device Distributor or PKRT Importer in Indonesia.
10. Product Owner means any company formed as legal entity or business entity, either as formula owner, designer, trade name owner or brand owner.
11. Medical Devices Distributor (*Penyalur Alat Kesehatan*), hereinafter abbreviated to PAK, means any company formed as legal entity in the form of Limited Liability Company or Cooperative that owns a license for the supply, storage, and distribution of Medical Devices and In Vitro Diagnostic Medical Devices.
12. PKRT Importer means any company formed as business entity that owns a license to import PKRT.
13. *Makloon* means a delegation in part or all of activity in the making of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT from Producer as Product Owner which owns Production Certificate to any other Producer which has owned such Production Certificate.
14. Original Equipment Manufacturer, hereinafter abbreviated to OEM, means a production activity conducted by Producer/Manufacturer, at the request of

PAK or PKRT Company as Product Owner by using trademark from the Product Owner.

15. Sole Agent/Sole Distributor/Exclusive Distributor means a PAK or PKRT Importer appointed by Producer or Manufacturer or Principal, to act as representative to register and distribute Medical Devices, In Vitro Diagnostic Medical Devices and PKRT within the territory of the Republic of Indonesia and to provide after-sales service on the Medical Devices, In Vitro Diagnostic Medical Devices and PKRT where such appointment is conducted on the basis of authorization with certain limitation to act for and on behalf of the Producer or Manufacturer or Principal.
16. Assembling means a series of activity to form Medical Devices, In Vitro Diagnostic Medical Devices and PKRT from non-assembled products, semi-finished products, and/or with constituent components originating from local components and/or imported components.
17. Repackaging means a series of activity to produce a product that includes wrapping, labeling and marking, without changing the raw material/formula, specification and intended use of the product.
18. Certificate of Free Sale, hereinafter abbreviated to CFS, means a certificate issued by the appropriate agency of a country that certifies that the Medical Devices, In Vitro Diagnostic Medical Devices and PKRT have obtained Product License and have been free sale in the country.
19. Import means an activity to bring Medical Devices, In Vitro Diagnostic Medical Devices and PKRT into customs area.
20. Export means an activity to bring Medical Devices, In Vitro Diagnostic Medical Devices and PKRT out of customs area.
21. Labeling means an objective, complete and non-misleading information in the form of figure, color, writing or combination in between or all three or any other forms included in packaging or put into packaging, or being a part of container and/or packaging.

22. Adverse Event (*Kejadian yang Tidak Diinginkan*), hereinafter abbreviated to KTD, means any malfunction, a deterioration in the characteristics/performance or use error of Medical Devices and In Vitro Diagnostic Medical Devices, which either can cause or contribute to death, or injury to health of patients or other persons.
23. Director General means a Director General in the Ministry of Health whose duties and responsibilities are in the field of Pharmaceuticals and Medical Devices.
24. Central Government, hereinafter referred to as Government, means the President of the Republic of Indonesia who holds the sovereignty of the Government of the Republic of Indonesia as referred to in the 1945 Constitution of the Republic of Indonesia.
25. Local Government means the head of region as the element of local governance who leads the execution of government affairs constituting the authority of autonomous region.
26. Minister means a Minister administering government affairs in the field of Health.

Article 2

Other than Medical Devices as referred to in Article 1 section 2, the Medical Devices also include reagent in vitro and calibrator, software, substance or material used solely or in combination, in order to prevent conception, disinfect medical Devices, and examine in vitro any specimen from human body, and those may contain drug which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

CHAPTER II
PRODUCT LICENSE ADMINISTRATION

Part One

General

Article 3

- (1) Product license Administration is intended to ensure that any Medical Devices, In Vitro Diagnostic Medical Devices and PKRT comply with the standard and/or requirements of safety, quality, and efficacy/performance.
- (2) The standard and/or requirements of safety, quality, and efficacy/performance as referred to in section (1) are complied from manufacture process until the use of the Medical Devices, In Vitro Diagnostic Medical Devices and PKRT.

Article 4

- (1) Any Medical Devices, In Vitro Diagnostic Medical Devices and PKRT which are produced, imported, assembled and/or repackaged for distribution within the territory of the Republic of Indonesia must have Product License.
- (2) Product license as referred to in section (1) is issued by Minister.
- (3) Minister delegates the issuance of the Product license as referred to in section (2) to Director General.

Article 5

The following Devices are excluded from the provision of Product license as referred to in Article 4:

- a. Any Medical Devices and In Vitro Diagnostic Medical Devices which enter into the territory of the Republic of Indonesia through the mechanism of Special Access Scheme in accordance with the provisions of the legislation;

- b. Certain Medical Devices and PKRT which are produced by home industry; and/or
- c. Any Medical Devices, In Vitro Diagnostic Medical Devices and PKRT due to certain reason determined by Minister.

Article 6

Any Medical Devices, In Vitro Diagnostic Medical Devices and PKRT for which the Product license is issued must comply with following criteria:

- a. quality, according to good manufacturing practice;
- b. safety and efficacy/performance, as proven by clinical evaluation report and/or any other evidences required;
- c. dosage, not exceeding a specified content limit in accordance with the prevailing standard, requirements and provision; and
- d. not using any prohibited material pursuant to the prevailing standard, requirements and provision

Article 7

- (1) Based on risks caused by the use of Medical Devices to patients, the Medical Devices are classified into:
 - a. class A, low risk level;
 - b. class B, low to moderate risk level;
 - c. class C, moderate to high risk level; and
 - d. class D, high risk level.
- (2) Based on risks due to misinterpretation to the results of examination on individual and the public, In Vitro Diagnostic Medical Devices are classified into:
 - a. class A, low risk level on individual and the public;
 - b. class B, moderate risk level on individual and low risk level on the public;
 - c. class C, high risk level on individual and moderate risk level on the public; and
 - d. class D, high risk level on individual and the public.
- (3) Based on risks caused by the use of PKRT to users, PKRT are classified into:

- a. class 1, low risk level;
 - b. class 2, moderate risk level; and
 - c. class 3, high risk level.
- (4) Further provisions on the classification of Medical Devices, In Vitro Diagnostic Medical Devices, and PKRT as referred to in section (1), section (2), and section (3) are regulated in the Regulation of Director General.

Article 8

Each class of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT as referred to in Article 7 is divided into category and sub-category listed in Annex I as an integral part of this Ministerial Regulation.

Part Two

Application for Product license

Paragraph One

General

Article 9

- (1) Application for the Product License of domestic Medical Devices, In Vitro Diagnostic Medical Devices and PKRT is submitted by:
- a. Producer;
 - b. Producer which provides *Makloon*;
 - c. Producer which conducts Assembling;
 - d. PAK as Product Owner which enters into a cooperation agreement with Producer; or
 - e. Producer producing Medical Devices, In Vitro Diagnostic Medical Devices and PKRT conducts OEM.
- (2) Application for the Product license of PKRT is excluded from the provision of section (1) point d.

Article 10

Application for the Product License of Imported Medical Devices, In Vitro Diagnostic Medical Devices and PKRT is submitted by:

- a. Sole Agent/Sole Distributor/Exclusive Distributor;
- b. PAK or PKRT Importer which owns a written appointment from Manufacturer or Principal and is authorized to register the Medical Devices, In Vitro Diagnostic Medical Devices and PKRT in Indonesia;
- c. PAK or PKRT Importer as Product Owners that own a written agreement with Manufacturer;
- d. PAK which conducts Assembling; or
- e. PAK which conducts Repackaging.

Article 11

Producer which conducts Assembling as referred to in Article 9 section (1) point c must fulfill the following criteria:

- a. any components which are the main function of finished products are manufactured domestically;
- b. in composition local components is more dominant than imported components; and/or
- c. Production processes are mostly carried out domestically.

Article 12

PAK which conducts Assembling and Repackaging as referred to in Article 9 section (1) point d and point e must fulfill the following criteria:

- a. owns Production Certificate; and
- b. owns a power of attorney from Manufacturer.

Article 13

Each type of Imported Medical Devices, In Vitro Diagnostic Medical Devices and PKRT under 1 (one) trade name/brand name originating from Manufacturer or Principal is authorized only by 1 (one) PAK or 1 (one) Importer of PKRT.

Article 14

- (1) Application for the Product license of Imported Medical Devices, In Vitro Diagnostic Medical Devices and PKRT must be accompanied by CFS issued by a Health Authority in the country of origin in which the Medical Devices, In Vitro Diagnostic Medical Devices and PKRT are produced.
- (2) In the event that the health authority in the country of origin in which the Medical Devices, In Vitro Diagnostic Medical Devices and PKRT are produced as referred to in section (1) cannot issue the CFS, the CFS is be issued by other health authority in a country which has regulation in the fields of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT.
- (3) In the event that the Medical Devices, In Vitro Diagnostic Medical Devices or PKRT as referred to in section (1) are not registered in the country of origin, the CFS may be issued by any other authority in the country of origin.
- (4) The CFS as referred to in section (1), section (2), and section (3) at least contains:
 - a. trade name/brand name;
 - b. type of product;
 - c. name and address of Manufacturer; and
 - d. period of validity.

Article 15

- (1) Producer is prohibited from registering the type of Imported Medical Devices, In Vitro Diagnostic Medical Devices and PKRT which is the same as the type of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT produces by it.
- (2) In the event of the type of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT as referred to in section (1) having different product specification may be registered by Producer affiliated to Manufacturer.
- (3) PAK or PKRT Importer which conducts OEM domestically is prohibited from registering the Medical Devices, In

Vitro Diagnostic Medical Devices and PKRT under the same type and specification as those of the Imported Medical Devices, In Vitro Diagnostic Medical Devices and PKRT which it distributes.

Article 16

- (1) Medical Devices, In Vitro Diagnostic Medical Devices and PKRT obtained through OEM must have different formula/design from the same type of product owned by the Producer/Manufacturer of the OEM.
- (2) In the event that the Medical Devices, In Vitro Diagnostic Medical Devices and PKRT cannot be produced domestically, a Product License for Imported OEM products may be issued.

Article 17

Application for the Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT consists of:

- a. new application;
- b. application for renewal;
- c. application for variation; and
- d. application for renewal with variation.

Paragraph Two

Procedures of New Application for Product License

Article 18

- (1) New application for the Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT as referred to in Article 17 point a is submitted online through Indonesian National Single Window portal or website address [regalkes.kemkes. go.id](http://regalkes.kemkes.go.id).
- (2) New application for the Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT as referred to in section (1) is completed with administrative and technical requirements stated in Annex II as an integral part of this Ministerial Regulation.

- (3) Applicant is responsible for the completeness, authenticity and validity of any application documents uploaded in electronic system.

Article 19

- (1) Director General conducts evaluation and verification on administrative and technical requirements as referred to in Article 18 section (2) to each application for the Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT.
- (2) In the event that the Medical Devices, In Vitro Diagnostic Medical Devices and PKRT as referred to in section (1) apply new technology, new active substance and/or with uncommon claim, a consideration from Expert Team assigned by the Director General must be provided.
- (3) The Expert Team as referred to in section (2) comprises of persons from relevant government agency, practitioner, university, professional organization and/or business association.

Article 20

- (1) Evaluation and verification on administrative and technical requirements as referred to in Article 19 to application for the Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT are carried out in accordance with a specified period.
- (2) Period of evaluation and verification on administrative and technical requirements as referred to in section (1) is different between local and imported Medical Devices, In Vitro Diagnostic Medical Devices and PKRT.
- (3) Period of evaluation and verification on administrative and technical requirements for local Medical Devices, In Vitro Diagnostic Medical Devices and PKRT as referred to in section (2) are executed as follows:
 - a. class A Medical Devices and In Vitro Diagnostic Medical Devices are not later than 10 (ten) days, whereas class B and class C are not later than 20 (twenty) days, and class D is not later than 30 (thirty) days;

- b. class 1 PKRT is not later than 10 (ten) days, whereas class 2 is not later than 20 (twenty) days, and class 3 is not later than 30 (thirty) days.
- (4) Period of evaluation and verification on administrative and technical requirements for the Imported Medical Devices, In Vitro Diagnostic Medical Devices and PKRTas referred to in section (2) are executed as follows:
- a. class A Medical Devices and In Vitro Diagnostic Medical Devices are not later than 15 (fifteen) days, whereas class B and class C are not later than 30 (thirty) days, and Class D is not later than 45 (forty-five) days;
 - b. class 1 PKRT is not later than 15 (fifteen) days, whereas class 2 is not later than 30 (thirty) days, and class 3 is not later than 45 (forty-five) days.
- (5) Based on the results of evaluation and verification as referred to in section (3) and section (4), after being declared complete and having fulfilled any administrative and technical requirements, Director General issues a Product License not later than 10 (ten) days.

Article 21

- (1) If required, after evaluation and verification on the completeness of administrative and/or technical requirements as referred to in Article 20, Director General notifies applicant of any additional enquiries to complete such requirements.
- (2) In terms of notification on additional enquiries to complete such requirements as referred to in section (1), the applicant has opportunity to complete the requirements not later than:
- a. 10 (ten) days as of the date of submission of the notification for class A, class B, and class C Medical Devices and In Vitro Diagnostic Medical Devices , and class 1, class 2, and class 3 PKRT of; and
 - b. 15 (fifteen) days as of the date of submission of the notification for Class D Medical Devices and In Vitro Diagnostic Medical Devices.

- (3) Director General conducts evaluation and verification on additional enquiries for the completeness of requirements as referred to in section (2) not later than of 10 (ten) days.
- (4) Based on the results of the evaluation and verification as referred to in section (3) an application is declared complete and having fulfilled any administrative and technical requirements, Director General issues a Product License not later than 10 (ten) days.
- (5) Based on the results of evaluation and verification as referred to in section (3), an application is declared having failed to fulfill any administrative and technical requirements and/or having failed to fulfill any additional data for the completeness of the requirements as referred to in section (2), the Director General issues a letter of rejection.

Article 22

- (1) Product License as referred to in Article 20 section (5) and Article 21 section (4) is issued in electronic form, not requiring stamp and manual signature.
- (2) The letter of rejection as referred to in Article 21 section (5) is submitted online and may be accessed through Indonesia National Single Window system or website address regalkes.kemkes.go.id.
- (3) Product License may be printed by applicant or any other relevant agency through Indonesia National Single Window system or website address regalkes.kemkes.go.id.
- (4) In the event of force majeure, the Product License may be issued manually.

Paragraph Three

Costs

Article 23

- (1) Any application for registration of the Product License of Medical Devices, In Vitro Diagnostic Medical Devices and

PKRT is subject to fees serving as non-tax state revenue in accordance with the provisions of legislation.

- (2) Payment of the non-tax state revenue as referred to in section (1) is made by the mechanism of e-payment.
- (3) In the event of force majeure, the payment of the non-tax state revenue (PNBP) may be made manually.
- (4) The non-tax state revenue which has been paid may not be withdrawn.

Paragraph Four
Period of Validity of Product License

Article 24

- (1) Distribution License is valid for a maximum of 5 (five) years.
- (2) In the event that application for Product License is submitted by PAK or PKRT Company appointed as Sole Agent/Sole Distributor/Exclusive Distributor and/or authorized for registration, the period of validity of the Product License follows the period of validity of such appointment or authorization.
- (3) The appointment and/or authorization as referred to in section (2) must be valid for not sooner than 2 (two) years and not later than 5 (five) years.
- (4) If appointment and/or authorization does not have the deadline or have the period of validity for more than 5 (five) years, Product License is valid for 5 (five) years as of the date of the appointment and/or authorization.
- (5) In the event that Medical Devices, In Vitro Diagnostic Medical Devices and PKRT are produced by Manufacturer through OEM, their Product License has the period of validity not later than 3 (three) years.
- (6) The period of validity of the Product License may be renewed as long as any requirements are fulfilled.

Article 25

Product License is declared invalid if:

- a. Product License expires;
- b. Production Certificate expires;
- c. PAK license expires;
- d. appointment as Sole Agent/Sole Distributor/Exclusive Distributor and/or authorization expires or is not extended; or
- e. Product License is revoked.

Paragraph Five

Renewal of Product License

Article 26

- (1) Product License holder who intends to renew the Product License must submit application for the renewal of the Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT not sooner than 9 (nine) months before its expiry.
- (2) Product License holder as referred to in section (1) must prepare Production or distribution report electronically through e-report system before the submission of application for the renewal of the Product License.
- (3) Any Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT produced through Imported OEM may be renewed 1 (one) time only.
- (4) Renewal of Product License of Imported OEM for Medical Devices, In Vitro Diagnostic Medical Devices and PKRT as referred to in section (3) must be done through review by considering the capacity of domestic industry to produce any products of the same type.
- (5) Product License holder submitting application for the renewal of Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT after expired follows any provisions on new application for the Product License.

- (6) If validity of Product License expires and has not yet been approved for renewal, the Medical Devices, In Vitro Diagnostic Medical Devices and PKRT are prohibited from being distributed.

Article 27

- (1) Application for the renewal of Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT as referred to in Article 26 section (1) is submitted online through Indonesian National Single Window portal or website address regalkes.kemkes.go.id.
- (2) Application for the renewal of Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT may not be processed if the status of Production or distribution report is nil within 2 (two) years before the Product license expires.
- (3) Application for the renewal of Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT as referred to in section (1) is completed with administrative and technical requirements stated in Annex II as an integral part of this Ministerial Regulation.
- (4) Applicant is responsible for the completeness, authenticity and validity of any application documents uploaded in electronic system.

Article 28

- (1) Director General conducts evaluation and verification on administrative and technical requirements as referred to in Article 27 section (3) to any application for the renewal of Product license of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT.
- (2) The evaluation and verification as referred to in section (1) are conducted not later than 7 (seven) days.
- (3) Based on the results of evaluation and verification on application for the renewal of Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT as referred to in section (1) and section (2), the application is

declared complete and having fulfilled any administrative and technical requirements, the Director General issues the Product License not later than 10 (ten) days.

Article 29

- (1) If required, after the evaluation and verification on the completeness of administrative and/or technical requirements as referred to in Article 28, Director General notifies applicant of any additional enquiries to complete such requirements.
- (2) In terms of notification on additional enquiries to complete such requirements as referred to in section (1) the applicant has opportunity to complete the requirements not later than 10 (ten) days as of the date of submission of the notification.
- (3) Director General conducts evaluation and verification on additional enquiries for the completeness of requirements as referred to in section (2) not later than 7 (seven) days as of the date of receipt of the additional requirements.
- (4) If based on the results of the evaluation and verification on application for the Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRTas referred to in section (3) the application is declared complete and having fulfilled any administrative and technical requirements, the Director General issues the Product License not later than 10 (ten) days.
- (5) If based on the results of the evaluation and verification an application is declared having failed to fulfill any administrative and technical requirements and/or having failed to fulfill any additional data for the completeness of the requirements as referred to in section (2) hereof, the Director General issues a letter of rejection.

Paragraph Six
Variation of Product License

Article 30

- (1) Variation of Product license is made if there is any change of:
 - a. size;
 - b. packaging;
 - c. labelling;
 - d. accessories/annex of the product license; and/or
 - e. name and/or address of representative authorized by Manufacturer.
- (2) The variation of Product License as referred to in section (1) is made without changing the Product License number.
- (3) In the event there is any change other than those referred to in section (1), new application for the Product License as referred to in Article 18 must be submitted.

Article 31

- (1) In the event that a variation affects the label of all products from Producer or Manufacturer but does not affect the safety, quality, and efficacy/performance of the products, the Product License holder must submit notification to Director General.
- (2) Upon the notification as referred to in section (1), Director General provides response not later than 7 (seven) days from the receipt of the notification.

Article 32

- (1) Application for the variation of Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT is submitted online through Indonesian National Single Window portal or website address regalkes.kemkes.go.id.
- (2) Application for the variation of Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT as referred to in section (1) completed with administrative

and technical requirements is listed in Annex II as an integral part of this Ministerial Regulation.

- (3) Applicant is responsible for the completeness, authenticity and validity of any application documents uploaded in electronic system.

Article 33

- (1) Director General conducts evaluation and verification on the administrative and technical requirements as referred to in Article 32 section (2) to any application for the variation of Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT.
- (2) Evaluation and verification as referred to in section (1) are carried out not later than 10 (ten) days.
- (3) Based on the results of evaluation and verification to application for the variation of Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT as referred to in section (1) and section (2), the application is declared complete and having fulfilled any administrative and technical requirements, Director General issues the Product License not later than 10 (ten) days.

Article 34

- (1) If required, after evaluation and verification on the completeness of administrative and/or technical requirements as referred to in Article 33, Director General notifies applicant of any additional enquiries to complete such requirements.
- (2) In terms of notification on additional enquiries to complete such requirements as referred to in section (1), the applicant has opportunity to complete the requirements not later than 10 (ten) days as of the date of submission of the notification.
- (3) Director General conducts evaluation and verification on additional enquiries for the completeness of requirements as referred to in section (2) not later than 10 (ten) days as of the date of receipt of the additional enquiries.

- (4) Based on the results of the evaluation and verification on application for the Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT as referred to in section (3), the application is declared complete and having fulfilled any administrative and technical requirements, then the Director General issues the Product License not later than 10 (ten) days.
- (5) Based on the results of the evaluation and verification, the application is declared having failed to fulfill any administrative and technical requirements and/or having failed to fulfill any additional data for the completeness of the requirements as referred to in section (2), the Director General issues a letter of rejection.

Paragraph Seven

Renewal with Variation of Product License

Article 35

- (1) Application for renewal with the variation of Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT is submitted online through Indonesian National Single Window portal or website address regalkes.kemkes.go.id.
- (2) Application for renewal with the variation of Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT complies with the provisions as referred to in Article 26.
- (3) Application for renewal with the variation of Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT may not be processed if the status of production or distribution report is nil within 2 (two) years before the Product License expires.
- (4) Application for renewal with the variation of Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT as referred to in section (1) completed with administrative and technical requirements is listed in Annex II as an integral part of this Ministerial Regulation.

- (5) Applicant is responsible for the completeness, authenticity and validity of any application documents uploaded in electronic system.

Article 36

- (1) Director General conducts evaluation and verification on administrative and technical requirements as referred to in Article 35 section (4) to any application for renewal with the variation of Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT.
- (2) The evaluation and verification as referred to in section (1) are conducted not later than 10 (ten) days.
- (3) Based on the results of evaluation and verification on application for renewal with the variation of Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT as referred to in section (1) and section (2), the application is declared complete and having fulfilled any administrative and technical requirements, the Director General issues the Product License not later than 10 (ten) days.

Article 37

- (1) If required, after the evaluation and verification on the completeness of administrative and/or technical requirements as referred to in Article 36, Director General notifies applicant of any additional enquiries to complete such requirements.
- (2) In terms of notification on additional enquiries to complete such requirements as referred to in section (1), the applicant has opportunity to complete the requirements not later than 10 (ten) days as of the date of submission of the notification.
- (3) Director General conducts evaluation and verification on additional enquiries for the completeness of requirements as referred to in section (2) not later than 10 (ten) days as of the date of receipt of the additional enquiries.

- (4) Based on the results of the evaluation and verification on application for the Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT as referred to in section (3), the application is declared complete and having fulfilled any administrative and technical requirements, the Director General issues the Product License not later than 10 (ten) days.
- (5) Based on the results of the evaluation and verification, the application is declared having failed to fulfill any administrative and technical requirements and/or having failed to fulfill any additional data for the completeness of the requirements as referred to in section (2), the Director General issues a letter of rejection.

Article 38

Further provisions regarding the procedures for evaluation and verification to application for the Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT are regulated in the Regulation of the Director General.

CHAPTER III

LABELING AND INFORMATION ON MEDICAL DEVICES, IN VITRO DIAGNOSTIC MEDICAL DEVICES AND HOUSEHOLD HEALTH PRODUCTS

Article 39

Labeling and information on Medical Devices, In Vitro Diagnostic Medical Devices and PKRT are carried out to protect the public from non-objective, incomplete and misleading information.

Article 40

Producer, PAK, or PKRT Importer which intend to distribute Medical Devices, In Vitro Diagnostic Medical Devices and PKRT must include the labeling and information on the Medical Devices, In Vitro Diagnostic Medical Devices and PKRT.

Article 41

- (1) Labeling and information on Medical Devices, In Vitro Diagnostic Medical Devices and PKRT which must be included as referred to in Article 40 must fulfill any conditions to insert any information of safety, efficacy/performance, instruction for use and/or any other information required.
- (2) Information as referred to in section (1) on Medical Devices and In Vitro Diagnostic Medical Devices at least states:
 - a. trade name/brand name;
 - b. Product license Number;
 - c. type of product;
 - d. name and address of Producer/Manufacturer;
 - e. name and address of PAK as the Product license holder;
 - f. batch number/Production code/serial number;
 - g. the word “sterile” and how to sterilize for sterile product;
 - h. product specification;
 - i. objective of use and instruction for use;
 - j. expiration date, for any products with expiration date; and
 - k. warning label, e.g “Professional Use Only” or letter symbol “P” colored white with black background for certain Medical Devices and In Vitro Diagnostic Medical Devices which must be used by competent person only.
- (3) In the event that the Medical Devices, In Vitro Diagnostic Medical Devices and PKRT contain statement on net, composition and content of active material, contra indication, caution and warning label or KTD/side effect, the label and information must state the same.
- (4) The information as referred to in section (1) on PKRT at least states:
 - a. trade name/brand name;
 - b. Product License number;

- c. type and variant of product;
 - d. net weight or net content;
 - e. name and address of Producer/Manufacturer which produces and/or;
 - f. name and address of PKRT Importer;
 - g. list of active materials used and their percentage;
 - h. expiration date for any products with expiration date;
 - i. Production code;
 - j. intended use;
 - k. instruction for use/preparation; and
 - l. caution and warning.
- (5) In addition to those as referred to in section (4), information on PKRT under the category of pesticide for household must also states:
- a. the suggestion “Not for use by children under 6 years old” for anti-mosquito product with pesticide spray and repellent to contact directly with skin; or
 - b. the suggestion “Not for use by children under 2 years old” for anti-mosquito product with pesticide patch (taped to the skin).
- (6) Information as referred to in section (2), section (3), and section (4), particularly for the objective of use/intended use, instruction for use, contra indication, caution and warning must be stated in Bahasa Indonesia.
- (7) Use of other than Bahasa Indonesian is allowed as long as there is no equivalent word or it is impossible to create the equivalent word or it is for overseas trade.
- (8) Labeling and information on Medical Devices, In Vitro Diagnostic Medical Devices and PKRT are prohibited from using the following words:
- a. superlative words such as “the most”, “very”, “number one”, “the only”, “top”, “effective”, “super”, “superior”, “amazing”, “magic”, “perfect” or the words with the suffix “-est (the most)”, and/or of the same meaning that explain such superiority;

- b. use of words such as “germ-free”, “mosquito-free”, “safe”, “eradicate”, “aromatherapy”, “anti-aging”, “treat”, “prevent dengue fever”, “antivirus”, “relaxation”, “recommended by doctor”, and/or any other words of the same meaning;
- c. writing of percentage or other statement to declare the effectiveness of product;
- d. use of the words “family”, “kids”, “baby”, “soft”, “moisturize” and/or any other words of the same meaning in any products of pesticide for household;
- e. use of claim “anti-bacteria”, not constituting the main intended use of product and placed at the front side of the label;
- f. use of claim “insect repellent” and/or any other words of the same meaning except in the product of pesticide for household and camphor;
- g. statement on additional substance function as main claim;
- h. statement on the name of examination laboratory; and/or
- i. statement on claim not conforming to active substance function as main claim.

CHAPTER IV QUALITY MAINTENANCE

Article 42

- (1) In order to maintain the quality of Medical Devices, In Vitro Diagnostic Medical Devices and/or PKRT, the Director General specifies:
 - a. requirements of quality maintenance of the Medical Devices, In Vitro Diagnostic Medical Devices and/or PKRT.
 - b. development and control of quality maintenance of the Medical Devices, In Vitro Diagnostic Medical Devices and/or PKRT.

- (2) Further provisions regarding quality maintenance efforts as referred to in section (1) are regulated in the Regulation of Director General.

Article 43

In order to ensure the quality, safety, and efficacy/performance of active devices and radiology, periodic calibration is necessary to be done in accordance with provisions of legislation.

CHAPTER V IMPORT AND EXPORT

Article 44

- (1) Import of Medical Devices and In Vitro Diagnostic Medical Devices may be carried out only by any company that possesses PAK license and Product License for the imported Medical Devices and In Vitro Diagnostic Medical Devices.
- (2) Import of PKRT may be carried out only by PKRT Importer that possesses Product License for the imported PKRT.
- (3) Import of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT through Indonesian National Single Window portal is carried out in accordance with the provisions of legislation.

Article 45

Export of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT may be carried out only by PAK that possesses Product License or by Producer.

Article 46

- (1) In special condition to meet the patient needs, increase of certain health service, and research, the Director General may issue the statement letter of Import or Export.

- (2) Statement letter of Import or Export as referred to in section (1) is issued by considering public interests, quality, safety, and efficacy/performance of the Imported and Exported Medical Devices, In Vitro Diagnostic Medical Devices and PKRT.
- (3) Further provisions regarding the statement letter of Import or Export as referred to in section (1) are issued by Minister.

Article 47

In order to increase and develop local products, testing for the purpose of Product License issuance, and exhibition for Re-export, Director General may issue the statement letter of Import.

Article 48

Any used Medical Devices, In Vitro Diagnostic Medical Devices and PKRT, including those reconditioned, refurbished and/or remanufactured are prohibited from being imported, used and/or distributed within the territory of the Republic of Indonesia.

CHAPTER VI

TRANSITION AND/OR TERMINATION OF APPOINTMENT OR AUTHORIZATION OF AGENCY

Article 49

- (1) Transition and/or termination of appointment or authorization of an agency may be carried out by Manufacturer or Principal to any PAK, PKRT company or PKRT Importer.
- (2) Transition and/or termination of appointment or authorization of an agency as referred to in section (1) may be carried out after Product License has expired or upon agreement of the parties.
- (3) Any new PAK, PKRT company or PKRT Importer that has been appointed or authorized by Manufacturer or

Principal as referred to in section (1) must submit notification on such transition and/or termination of appointment or authorization of an agency, to Director General within not later than 30 (thirty) days as of the date of the appointment of agency or authorization.

- (4) In the event of failure to reach an agreement of the parties as referred to in section (2), which may result in the dispute of agency, settlement must be done within not later than 6 (six) months from the submission of notification to guarantee the distribution and health services.
- (5) If failure to settle the dispute of agency within such timeframe as referred to in section (3), Director General determines to approve the revocation of Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT.

CHAPTER VII PUBLIC PARTICIPATION

Article 50

- (1) Public participation may be done by individual, group, or non-government organization.
- (2) Public participation is directed to increase and empower the ability in the public for the safety of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT.

CHAPTER VIII REPORTING

Article 51

- (1) Each Product License holder must submit production or distribution report to Director General through e-report for Medical Devices and PKRT.
- (2) In addition to the report as referred to in section (1), the Product License holder must submit KTD Report in case of any adverse event, through e-watch for Medical Devices and PKRT.

CHAPTER IX
DEVELOPMENT AND CONTROL

Part One
Development

Article 52

- (1) Central Government, Provincial Government, and Regency/Municipal Government carry out the development of this Ministerial Regulation according to their respective duties and functions.
- (2) Development as referred to in section (1) is aimed:
 - a. to meet the quantity and type of public needs on Medical Devices, In Vitro Diagnostic Medical Devices and PKRT;
 - b. to protect the public from the danger of misuse and abuse of the Medical Devices, In Vitro Diagnostic Medical Devices and PKRT;
 - c. to protect the public from the danger of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT not fulfilling any requirements of safety, quality, and efficacy/performance; and
 - d. to guarantee the fulfillment or maintenance of the requirements of safety, quality, and efficacy/performance of the distributed Medical Devices, In Vitro Diagnostic Medical Devices and PKRT.
- (3) Development as referred to in section (1) is carried out in the fields of:
 - a. fulfillment of requirements of Product License;
 - b. human resources;
 - c. products information; and
 - d. advertising.

Part Two
Control

Article 53

- (1) Central Government, Provincial Government, and Regency/Municipal Government conduct control on the execution of this Ministerial Regulation according to their respective duties and functions.
- (2) Control as referred to in section (1) is in the form of:
 - a. audit on technical and clinical information;
 - b. inspection on the means of Production and distribution;
 - c. sampling and examination; and
 - d. control on labeling and advertising.
- (3) Further provisions regarding the procedures for execution of the control as referred to in section (1) and section (2) are regulated in Ministerial Regulation.

Article 54

- (1) Producer, PAK, PKRT company, and PKRT Importer must conduct the control of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT produced and/or distributed, in order to guarantee compatibility in their quality, safety, and efficacy/performance
- (2) Control by Producer, PAK, PKRT company, and PKRT Importer is in the form of:
 - a. audit on the information of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT obtained from the means of distribution/distributor;
 - b. re-inspection on products in order to find out KTD; and
 - c. reporting to Central Government, Provincial Government, and Regency/Municipal Government regarding the KTD.
- (3) Producer, PAK, PKRT company, and PKRT Importer must report on the results of the control as referred to in section (2) to Director General.

Article 55

Provincial Government and Regency/Municipal Government report in stages the results of development and control conducted, to Director General.

Part Three

Responsibility

Article 56

- (1) Any Medical Devices, In Vitro Diagnostic Medical Devices and PKRT which are sold under Product License are the responsibility of the Product License holder.
- (2) Any Medical Devices, In Vitro Diagnostic Medical Devices and PKRT produced through OEM are not only the responsibility of the Product License holder as referred to in section (1), but also are the responsibility of the Products Owner.
- (3) Any Medical Devices, In Vitro Diagnostic Medical Devices and PKRT which are the products of *Makloon* are not only the responsibility of the Product License holder as referred to in section (1), but also are the responsibility of a Producer that grants *Makloon*.

Part Four

Evaluation

Article 57

- (1) Central Government, Provincial Government, and Regency/Municipal Government carry out periodic evaluation on any Medical Devices, In Vitro Diagnostic Medical Devices and PKRT that have obtained Product License.
- (2) Evaluation as referred to in section (1) is conducted if based on the results of monitoring and evaluation there is any difference of data provided at the time of submission of application for registration of Product License.

- (3) In the event that there is any complaint from the public and/or KTD, the Central Government, Provincial Government, and Regency/Municipal Government carry out evaluation anytime.
- (4) Results of the evaluation as referred to in section (2) and section (3) may be in the form of recommendation on:
 - a. the change of labeling;
 - b. the change of composition/formula;
 - c. the limitation of use;
 - d. the recall of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT from distribution; and/or
 - e. the revocation of Product License.

CHAPTER X

RECALL AND DESTRUCTION

Part One

Recall

Article 58

- (1) Medical Devices, In Vitro Diagnostic Medical Devices and PKRT which fail to fulfill any requirements and/or which the Product License has been revoked, a recall is executed.
- (2) Recall of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT from distribution as referred to in section (1) is executed by and the responsibility of a company that produces and/or distributes the Medical Devices, In Vitro Diagnostic Medical Devices and PKRT.
- (3) Further provisions regarding the procedures for recall of the Medical Devices, In Vitro Diagnostic Medical Devices and PKRT from distribution as referred to in section (1) and section (2) are regulated by Director General.

Part Two
Destruction

Article 59

Destruction of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT is carried out to those which are:

- a. non-compliance with the requirements of safety, quality and efficacy/performance for use;
- b. expired;
- c. the Product License has been revoked;
- d. being produced and/or imported but not conforming to the provisions of legislation; and
- e. related to criminal action.

Article 60

- (1) Destruction of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT is carried out by Producer, PAK, PKRT Importer as Product License holder, health service facility, Central Government, Provincial Government, and/or Regency/Municipal Government.
- (2) Health service facility as referred to in section (1) owned by Central Government, Provincial Government, and Regency/Municipal Government must conduct write-off in accordance with the provisions of legislation in the field of management of assets owned by state/region.
- (3) Destruction of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT related to criminal action as referred to in Article 57 point e is carried out by appropriate government agency in accordance with the provisions of legislation.

Article 61

Destruction of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT is carried out by taking into account any impacts to human health and environment.

Article 62

Further provisions regarding the procedures of destruction are regulated in the Regulation of Director General.

CHAPTER XI

SANCTION

Article 63

- (1) Any violation of this Ministerial Regulation may be subject to administrative sanction.
- (2) The administrative sanction as referred to in section (1) is in the form of:
 - a. written warning;
 - b. suspension of activity; and
 - c. revocation of Product License.
- (3) Revocation of Product License as referred to in section (2) point c is executed if:
 - a. Medical Devices, In Vitro Diagnostic Medical Devices and PKRT cause effect that may endanger health;
 - b. incompliance of criteria according to data submitted in application for registration of Product License;
 - c. Production Certificate is revoked;
 - d. PAK license is revoked; or
 - e. termination of appointment as Sole Agent/Sole Distributor/Exclusive Distributor and/or authorization.
- (4) Further provisions regarding administrative sanction as referred to in section (1) and section (2) are regulated in the Regulation of Director General.

Article 64

Any violation of this Ministerial Regulation which results in someone's serious health problem, disability or death, or any forgery and/or distribution of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT without possessing Product License may be subject to criminal sanction under legislation.

CHAPTER XII
TRANSITIONAL PROVISIONS

Article 65

- (1) Application for the Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT which has been submitted before this Ministerial Regulation comes into force will be consistently processed under the Regulation of the Minister of Health Number 1190/MENKES/PER/VIII/2010 regarding the Product License of Medical Devices and Household Health Products.
- (2) Product License of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT which has been issued under Regulation of the Minister of Health Number 1190/MENKES/PER/VIII/2010 regarding the Product License of Medical Devices and Household Health Products is declared to remain effective until its expiration date.
- (3) Adjustment to the provisions of this Ministerial Regulation is conducted within not later than 2 (two) years since this Ministerial Regulation comes into force.

Article 66

At the time this Ministerial Regulation comes into force, the entire implementing regulations of Regulation of the Minister of Health Number 1190/MENKES/PER/VIII/2010 on Product License of Medical Devices and Household Health Products (State Bulletin of the Republic of Indonesia of of 2010 Number 400) are declared to remain effective to the extent not contrary to the provisions of this Ministerial Regulation and/or are not yet amended in accordance with the provisions of this Ministerial Regulation.

CHAPTER XIII
CLOSING PROVISIONS

Article 67

At the time this Regulation comes into force, Regulation of the Minister of Health Number 1190/MENKES/PER/VIII/2010 on Product License of Medical Devices and Household Health Products (State Bulletin of the Republic of Indonesia of 2010 Number 400) is repealed and declared ineffective.

Article 68

This Ministerial Regulation comes into force on the date of its promulgation.

In order that every person may know hereof, it is ordered to promulgate this Ministerial Regulation by its placement in the State Bulletin of the Republic of Indonesia.

Issued in Jakarta
on 29 December 2017

MINISTER OF HEALTH
OF THE REPUBLIC OF INDONESIA,

signed

NILA FARID MOELOEK

Promulgated in Jakarta
on 12 January 2018

DIRECTOR GENERAL OF LEGISLATION
OF MINISTRY OF LAWS AND HUMAN RIGHTS
OF THE REPUBLIC OF INDONESIA,

signed

WIDODO EKATJAHJANA

STATE BULLETIN OF THE REPUBLIC OF INDONESIA OF 2018 NUMBER 82

Jakarta, 16 December 2019

Has been translated as an Official Translation
on behalf of Minister of Law and Human Rights
of the Republic of Indonesia

DIRECTOR GENERAL OF LEGISLATION,



WIDODO EKATJAHJANA

ANNEX I
REGULATION OF THE MINISTER OF HEALTH OF
THE REPUBLIC OF INDONESIA
NUMBER 62 OF 2017
ON
PRODUCT LICENSE OF MEDICAL DEVICES, IN
VITRO DIAGNOSTIC MEDICAL DEVICES AND
HOUSEHOLD HEALTH PRODUCTS

CATEGORY AND SUBCATEGORY OF MEDICAL DEVICES, IN VITRO DIAGNOSTIC
MEDICAL DEVICES AND PKRT

- I. CATEGORY AND SUBCATEGORY OF MEDICAL DEVICES AND IN VITRO
DIAGNOSTIC MEDICAL DEVICES
 - A. CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES
 - 1. Clinical Chemistry Test Systems
 - 2. Clinical Laboratory Instruments
 - 3. Clinical Toxicology Test Systems
 - B. HEMATOLOGICAL AND PATHOLOGICAL DEVICES
 - 1. Biological Stains
 - 2. Cell and Tissue Culture Products
 - 3. Pathology Instrumentation and Accessories
 - 4. Specimen Preparation Reagents
 - 5. Automated and Semi-automated Hematology Devices
 - 6. Manual Hematology Devices
 - 7. Hematology Kits and Packages
 - 8. Hematology Reagents
 - 9. Products used in Establishments that Manufacture Blood
and Blood Products
 - C. IMMUNOLOGICAL AND MICROBIOLOGICAL DEVICES
 - 1. Diagnostic Devices
 - 2. Microbiology Devices
 - 3. Serological Reagents
 - 4. Immunology Laboratory Equipment and Reagents
 - 5. Immunological Test Systems
 - 6. Tumor Associated Antigen Immunological Test Systems

D. ANESTHESIOLOGY DEVICES

1. Anesthesiology Diagnostic Devices
2. Anesthesiology Monitoring Devices
3. Anesthesiology Therapeutic Devices
4. Miscellaneous Anesthesiology Devices

E. CARDIOVASCULAR DEVICES

1. Cardiovascular Diagnostic Devices
2. Cardiovascular Monitoring Devices
3. Cardiovascular Prosthetic Devices
4. Cardiovascular Surgical Devices
5. Cardiovascular Therapeutic Devices

F. DENTAL DEVICES

1. Dental Diagnostic Devices
2. Dental Prosthetic Devices
3. Dental Surgical Devices
4. Dental Therapeutic Devices
5. Miscellaneous Dental Devices

G. EAR, NOSE AND THROAT (ENT) DEVICES

1. ENT Diagnostic Devices
2. ENT Prosthetic Devices
3. ENT Surgical Devices
4. ENT Therapeutic Devices

H. GASTROENTEROLOGICAL - UROLOGICAL (GU) DEVICES

1. GU Diagnostic Devices
2. GU Monitoring Devices
3. GU Prosthetic Devices
4. GU Surgical Devices
5. GU Therapeutic Devices

I. GENERAL HOSPITAL AND PERSONNEL USE DEVICES

1. General Hospital and Personnel Use Monitoring Devices
2. General Hospital and Personnel Use Therapeutic Devices
3. General Hospital and Personnel Use Miscellaneous Devices

- J. NEUROLOGICAL DEVICES
 - 1. Neurological Diagnostic Devices
 - 2. Neurological Surgical Devices
 - 3. Neurological Therapeutic Devices

- K. OBSTETRICAL AND GYNECOLOGICAL DEVICES (OG)
 - 1. OG Diagnostic Devices
 - 2. OG Monitoring Devices
 - 3. OG Prosthetic Devices
 - 4. OG Surgical Devices
 - 5. OG Therapeutic Devices
 - 6. Assisted Reproduction Devices

- L. OPHTHALMIC DEVICES
 - 1. Ophthalmic Diagnostic Devices
 - 2. Ophthalmic Prosthetic Devices
 - 3. Ophthalmic Surgical Devices
 - 4. Ophthalmic Therapeutic Devices

- M. ORTHOPEDIC DEVICES
 - 1. Orthopedic Diagnostic Devices a
 - 2. Orthopedic Prosthetic Devices
 - 3. Orthopedic Surgical Devices

- N. PHYSICAL MEDICINE DEVICES
 - 1. Physical Medicine Diagnostic Devices
 - 2. Physical Medicine Prosthetic Devices
 - 3. Physical Medicine Therapeutic Devices

- O. RADIOLOGY DEVICES
 - 1. Radiology Diagnostic Devices
 - 2. Radiology Therapeutic Devices
 - 3. Miscellaneous Radiology Devices

- P. GENERAL AND PLASTIC SURGERY DEVICES
 - 1. Surgical Diagnostic Devices
 - 2. Surgical Prosthetic Devices

3. Surgical Devices
4. Surgical Therapeutic Devices

II. CATEGORY AND SUBCATEGORY OF PKRT

A. TISSUE AND COTTON

1. Cosmetic Cotton
2. Facial Tissue/Toilet Tissue
3. Facial Paper
4. Wet Tissue
5. Cotton Bud
6. Miscellaneous Tissue and Cotton

B. LAUNDRY PREPARATION

1. Laundry Soap and/or Laundry Enzyme
2. Detergent
3. Cloth Softener, Fragrance and/or Smoothing Preparation
4. Cloth Whitener
5. Miscellaneous Preparation for Laundry

C. CLEANER

1. Kitchen Utensil Cleaner
2. Glass Cleaner
3. Floor, Porcelain and/or Ceramic Cleaners
4. Metal Cleaner
5. Furniture Cleaner
6. Carpet Cleaner
7. Water Purifier
8. Conduit and Closet Cleaners
9. Hand Wash Soap
10. Miscellaneous Cleaners

D. BABY AND MOTHER CARE PRODUCTS

1. Milk Bottle and/or Nipple
2. Baby Diaper
3. Breast Milk Container
4. Disposable Breast Milk's Absorbent

E. ANTISEPTIC AND DISINFECTANT

1. Antiseptic
2. Disinfectant
3. Miscellaneous Antiseptic and Disinfectant

F. FRAGRANCE

1. Air Freshener
2. Car Perfume
3. Water and/or Smell Absorbent
4. Camphor
5. Miscellaneous Fragrances

G. HOUSEHOLD PESTICIDE

1. Insect Controller
2. Insect Repellent
3. Rat Controller
4. Miscellaneous Household Pesticides

MINISTER OF HEALTH
OF THE REPUBLIC OF
INDONESIA,

signed

NILA FARID MOELOEK

ANNEX II
REGULATION OF THE MINISTER OF HEALTH OF
THE REPUBLIC OF INDONESIA
NUMBER 62 OF 2017
ON
PRODUCT LICENSE OF MEDICAL DEVICES, IN
VITRO DIAGNOSTIC MEDICAL DEVICES AND
HOUSEHOLD HEALTH PRODUCTS

REQUIREMENTS OF APPLICATION FOR PRODUCT LICENSE OF MEDICAL
DEVICES, IN VITRO DIAGNOSTIC MEDICAL DEVICES, AND HOUSEHOLD
HEALTH PRODUCTS

- I. REQUIREMENTS OF NEW APPLICATION FOR PRODUCT LICENSE OF
MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES
 - A. ADMINISTRATIVE REQUIREMENTS
 1. Application for Registration
 2. Production Certificate/PAK Licence
 3. Power of Attorney as Sole Agent/Sole Distributor/Exclusive Distributor
 4. Certificate of Free Sale (CFS) from appropriate institution (imported products)
 5. Quality Management System Documents (ISO 13485, ISO 9001, CE)
 6. Trademark Certificate (if any)
 - B. TECHNICAL REQUIREMENTS
 1. PRODUCT INFORMATION
 - a. Material, formulation, device information, description and features of Medical Devices or In Vitro Diagnostic Medical Devices
 - b. Standard and production process
 - c. Indication, intended use, and instruction for use
 - d. Contra indication, warning, caution, undesirable potential effect
 2. SPECIFICATION REQUIREMENTS AND QUALITY ASSURANCE
 - a. Raw material specification and Material Safety Data Sheet (MSDS)

- b. Package specification
- c. Device performance specification
- d. Laboratory test results (Certificate of Analysis (CoA), stability test, sterility test, electricity safety test)
- e. Pre-clinical and clinical study results (for Class C and D Medical Devices and In Vitro Diagnostic Medical Devices)
- f. Risk management

3. SPECIAL REQUIREMENTS

- a. Radiation material safety
- b. Clinical Test on HIV products from national reference laboratory

4. LABELING REQUIREMENTS

- a. Sample and explanation of labeling
- b. Instruction for use, training material, and instruction for installation and maintenance

5. POST-MARKET REQUIREMENTS

Procedures for documentation and management of adverse event and complaint

II. REQUIREMENTS OF NEW APPLICATION FOR PRODUCT LICENSE OF HOUSEHOLD HEALTH PRODUCTS

A. ADMINISTRATIVE REQUIREMENTS

- 1. Application for Registration
- 2. Production Certificate
- 3. Power of Attorney as Sole Agent/Sole Distributor/Exclusive Distributor
- 4. Certificate of Free Sale (CFS) from appropriate institution (imported products)
- 5. Quality Management System Documents (ISO 9001, Good Manufacturing Practices/GMP)
- 6. Trademark Certificate (if any)

B. TECHNICAL REQUIREMENTS

1. PRODUCT INFORMATION

- a. Material, formulation, product information, description and features of product
- b. Standard and production process

2. SPECIFICATION REQUIREMENTS AND QUALITY ASSURANCE
 - a. Raw material specification and MSDS
 - b. Package specification
 - c. Laboratory test results (Certificate of Analysis (CoA), stability test)
 3. SPECIAL REQUIREMENT
License from the Ministry of Agriculture for Household Pesticide
 4. LABELING REQUIREMENTS
 - a. Sample and explanation of labeling
 - b. Instruction for use, warning, caution, and other information
 - c. Supporting data for claim
- III. REQUIREMENTS OF APPLICATION FOR RENEWAL, CHANGE, OR RENEWAL WITH CHANGE OF PRODUCT LICENSE OF MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES
- A. ADMINISTRATIVE REQUIREMENTS
 1. Application for Registration
 2. Production Certificate/PAK License
 3. Power of Attorney as Sole Agent/Sole Distributor/Exclusive Distributor
 4. Certificate of Free Sale (CFS) from appropriate institution (imported products)
 5. Quality Management System Documents (ISO 13485, ISO 9001, CE)
 6. Trademark Certificate (if any)
 - B. TECHNICAL REQUIREMENTS
 1. LABELING REQUIREMENTS
 - a. Sample and explanation of labeling
 - b. Instruction for use, training material, and instruction for installation and maintenance
 2. SPECIAL REQUIREMENTS
 - a. Radiation material safety
 - b. Clinical Test on HIV products from national reference laboratory

IV. REQUIREMENTS OF APPLICATION FOR RENEWAL, CHANGE, OR RENEWAL WITH CHANGE OF PRODUCT LICENSE OF HOUSEHOLD HEALTH PRODUCTS

A. ADMINISTRATIVE REQUIREMENTS

1. Application for Registration
2. Production Certificate
3. Power of Attorney as Sole Agent/Sole Distributor/Exclusive Distributor
4. Certificate of Free Sale (CFS) from appropriate institution (imported products)
5. Quality Management System Documents (ISO 9001, GMP)
6. Trademark Certificate (if any)

B. TECHNICAL REQUIREMENTS

1. LABELING REQUIREMENTS

- a. Sample and explanation of labeling
- b. Instruction for use, warning, caution, and other information
- c. Supporting data for claim

2. SPECIAL REQUIREMENT

License from the Ministry of Agriculture for Household Pesticide

MINISTER OF HEALTH
OF THE REPUBLIC OF
INDONESIA,

signed

NILA FARID MOELOEK