MENTERI KESEHATAN
REPUBLIK INDONESIA

REGULATION OF THE MINISTER OF HEALTH OF THE REPUBLIC OF INDONESIA
NUMBER 4 YEAR 2014

ABOUT

HOW TO DISTRIBUTE GOOD MEDICAL TOOLS

BY THE GRACE OF GOD ALMIGHTY

MINISTER OF HEALTH OF THE REPUBLIC OF INDONESIA,

Considering: that in order to implement the provisions of Article 33 paragraph (2) Regulation Minister Health Number 1191/Menkes/Per/VIII/2010 concerning Distribution of Equipment Health, it is necessary to stipulate a Ministerial Regulation Health regarding the Distribution of Medical Devices that are Well;

In view of: 1. Law Number 8 of 1999 concerning 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 32 of 2004 concerning Regional Government (State Gazette of the Republic of Indonesia of 2004 Number 125, Supplement to State Institutions of the Republic of Indonesia Number 4437) as last amended by Law Number 12 of 2008 (State Gazette of the Republic of Indonesia of 2008 Number 59 , Supplement to the State Institution of the Republic of Indonesia Number 4844);

3. Law Number 36 of 2009 concerning Health (State Gazette of the Republic of Indonesia of 2009 Number 144, Supplement to the State Gazette of the Republic of Indonesia Number 5063);

4. Law Number 3 of 2014 concerning Industry (State Gazette of the Republic of Indonesia of 2014 Number 4, Supplement to the State Gazette of the Republic of Indonesia Number 5492);

5. Rules ...

5. Government Regulation Number 72 of 1998 concerning Security of Pharmaceutical Preparations and Medical Devices (State Gazette of the Republic of Indonesia of 1998 Number 138, Supplement to the State Gazette of the Republic of Indonesia of 1998 Number 3781);

6. Government Regulation Number 38 of 2007 concerning the Division of Government Affairs between the Government, Provincial Government, and Regency/City Government (State Gazette of the Republic of Indonesia of 2007 Number 82, Supplement to the State Gazette of the Republic of Indonesia Number 4737);

7. Rules Minister Health Number 1144/Menkes/Per/lll/2010 concerning Organization and Ministry of Health Work Procedure (State News Republic of Indonesia Year 2010 Number 585) as amended by Ministerial Regulation Health Number 35 of 2013 (State Gazette Republic of Indonesia Year 2013 Number 741);

8. Rules Minister Health Number 1189/Menkes/Per/VIII/2010 concerning Tool Production Health and Household Health Supplies (State Gazette of the Republic of Indonesia of 2010 Number 399);

9. Rules Minister Health Number 1190/Menkes/Per/VIII/2010 concerning Device Distribution Permit Health and Household Health Supplies (State Gazette of the Republic of Indonesia of 2010 Number 400);

10. Rules Minister Health Number 1191/Menkes/Per/VIII/2010 concerning Distribution of Equipment Health (State Gazette of the Republic of Indonesia Year 2010 Number 401);

DECIDE:

To stipulate : REGULATION OF THE MINISTER OF HEALTH CONCERNING GOOD DISTRIBUTION OF MEDICAL EQUIPMENT.

article 1 ...

article 1

Good Method of Distribution of Medical Devices, hereinafter abbreviated as CDAKB, is a guideline used in a series of distribution and quality control activities aimed at ensuring that the distributed medical device products meet the requirements set for their intended use.

Section 2

(1) Every Medical Device Distributor and Medical Device Distribution Branch in carrying out distribution activities must implement CDAKB.

(2) CDAKB as referred to in paragraph (1) includes the following aspects:
a. quality management system;
b. resource management;
c. buildings and facilities;
d. inventory storage and handling;
e. product *traceability (traceability);*
f. complaint handling;
g. *Field Safety Corrective Action (FSCA) ;*
h. return/return of medical devices;
i. destruction of medical devices;
j. illegal and unqualified medical devices;
k. internal audits;
l. management studies; and
m. third party activities *(outsourcing activities).*

(3) CDAKB as referred to in paragraph (1) is listed in the Appendix which is an integral part of this Ministerial Regulation.

Article 3

The guidance and supervision of the implementation of this Ministerial Regulation is carried out by the Minister, the Head of the Provincial Health Office, the Head of the Regency/City Health Office according to their respective duties and functions.

Article 4 ...

MENTERI KESEHATAN
REPUBLIK INDONESIA

Article 4

This Ministerial Regulation comes into force on the date of promulgation

For public cognizance, ordering the promulgation of this Ministerial Regulation by placing it in the State Gazette of the Republic of Indonesia.

Stipulated in Jakarta on
27 January 2014

MINISTER OF HEALTH
REPUBLIC OF INDONESIA,

signed

MBOI'S NAFSIAH

Promulgated in Jakarta on
February 10, 2014

MINISTER OF LAW AND HUMAN RIGHTS
REPUBLIC OF INDONESIA,

signed

AMIR SYAMSUDDIN

STATE GAZETTE OF THE REPUBLIC OF INDONESIA YEAR 2014 NUMBER 194

MENTERI KESEHATAN
REPUBLIK INDONESIA

ATTACHMENT
REGULATION OF THE MINISTER OF HEALTH
REPUBLIC OF INDONESIA
NUMBER 4 YEAR 2014
ABOUT
HOW TO DISTRIBUTE TOOLS
GOOD HEALTH

HOW TO DISTRIBUTE GOOD MEDICAL TOOLS

I. Introduction

The safety, quality, and efficacy of medical devices may decrease due to improper handling during distribution activities. Medical Device Distributors (PAK) and PAK Branches have an important role in ensuring the safety, quality, and benefits of medical devices circulating in the community.

CDAKB is used by the Government in the context of granting certification to PAK and PAK Branches that carry out distribution activities of medical devices in accordance with the provisions of laws and regulations.

II. Definition

1. Medical Devices are instruments, apparatus, machines, and/or implants that do not contain drugs that are used to prevent, diagnose, cure and relieve disease, treat sick people, restore health to humans, and/or form structures and improve bodily functions.

2. Medical Device Distributor, hereinafter abbreviated as PAK, is a company in the form of a legal entity that has a license to procurement, storage, distribution of medical devices in large quantities in accordance with the provisions of the legislation.

3. Medical Device Distribution Branch, hereinafter abbreviated as PAK Branch, is a business unit of PAK that already has the recognition to carry out procurement, storage, distribution of medical devices in large quantities in accordance with the provisions of the legislation.

4. Electromedical Medical Devices are medical devices that use AC or DC power sources for their operation.
5. Radiation Electromedical Medical Devices are medical devices that use AC or DC power sources for operation and emit ionizing radiation or radioactive substances during use to achieve their intended use.
6. Non-Radiation Electromedical Medical Devices are medical devices that use AC or DC power sources for operation and do not emit ionizing radiation or radioactive substances during use to achieve their intended purpose.

   its use.
7. Non-Sterile Electromedical Medical Devices are medical devices whose use does not require an AC or DC power source and undergoes a sterilization process in the production process and the product is sterile. Example: syringe, sterile gauze, surgical thread, IV *catheter, infusion set.*
8. Non-Sterile Electromedical Medical Devices are medical devices whose use does not require an AC or DC power source and the product is not sterile. Examples: plasters, surgical instruments, baby scales, manual wheelchairs, manual patient beds, *statescopes.*
9. In Vitro Diagnostic Product is a medical device used for examination of specimens from inside the human body by In Vitro to provide information for diagnosis, monitoring or combination. This includes reagents, calibrators, control materials, specimen holders, *software,* and related instruments or tools or chemicals. Examples: blood sugar test kits, early pregnancy tests, uric acid tests, clinical chemistry test kits, *hematology analyzer.*
10. Illegal Medical Devices are medical devices that do not have a distribution permit, the import process is not in accordance with the provisions of laws and regulations, is not sourced from a single agent, and/or is counterfeit.
11. Unqualified Medical Devices are original medical devices that are produced not according to the standards set by the manufacturer.

III. Aspects of Good Distribution of Medical Devices

1. Quality Management System

a. General requirement

1) PAK and PAK Branches must have an organizational structure that is in accordance with the needs, equipped with a company chart and establish, document, implement and maintain a quality document system and maintain effectiveness related to CDAKB.

2) Each personnel must have clear responsibilities and authorities and personnel receive the necessary training to support the implementation of their duties and
his authority.

3) PAK and PAK Branches must have a competent, authorized and responsible technical person in charge so that the distribution system runs well to ensure the safety, quality and benefits of the distributed medical devices.

4) PAK and PAK Branches that distribute electromedical medical devices and in vitro diagnostic products must have competent technicians.

5) PAK and PAK Branches must have security procedures in distribution activities, including security of personnel, products, and equipment.

b. Documentation Requirements

1) PAK and PAK Branches must have standard operating procedures for the development, control, distribution and inspection of all documents related to the distribution process.

2) The title, nature and purpose of each document must be stated clearly and not ambiguous.

3) Documentation consists of passive and active documentation. Passive documentation systems include standard operating procedures and product specifications. Active documentation system, including receipt records, storage records, distribution records and sales records.

4) Passive documents must be created, approved and dated and must not be changed without approval by authorized personnel.

5) Active documents must include implementing personnel and inspection personnel.

6) Passive documents should be checked regularly and kept up to date. When a document has been revised, there must be a system in place to prevent the inadvertent use of the replaced version of the document.
7) Data can be recorded with electronic data processing systems but standard operating procedures related to the system used must be in place, and the accuracy of recordings must be checked.

8) The computerized document must comply with the regulations regarding electronic documentation.
9) A description of the system should be drawn up (including appropriate diagrams) and kept up to date. The description should describe the principles, objectives, security measures and scope of the system as well as the main features of the way the computer interacts with other systems and procedures.
10) Records should be easily retrieved, stored and maintained.
11) Records must be kept for a certain period of time determined based on the requirements/stipulations of the legislation or in accordance with the useful life of the *medical* device concerned as determined by the manufacturer of the medical device, but not less than 2 (two) years from the date of the medical device is sent from the company.

12) Distribution reporting is carried out at least once a year in accordance with the provisions of the legislation.

2. Resource Management

a. Personnel

1) Fully working technical person in charge, with a minimum education of Associate Pharmacist, MAdya Expert in Electrical Engineering, and/or other equivalent personnel, in accordance with the product being distributed.
2) The technical person in charge must have education, knowledge, skills, and experience in accordance with his responsibilities so that the products distributed are guaranteed safety, quality and benefits.

3) Personnel involved in distribution activities must wear safety attributes that are appropriate to the nature of the product and its activities. For example, medical devices contain hazardous materials or radiation.

4) Personnel must carry out procedures related to *hygiene.*
5) Records of each personnel must be maintained by the department personnel.
6) The company must appoint a management representative regardless of his/her main duties and main functions.

b. Training

1) All personnel must receive training related to CDAKB and laws and regulations, standard operating procedures and work safety issues in accordance with the planned training program.

2) Special training must be provided for personnel dealing with medical devices that are at high risk and/or can cause unwanted effects, such as infections and allergies.

3) The training that has been carried out must be evaluated.
4) Records of training must be maintained.

3. Buildings and Facilities

a. General Explanation

1) PAK and PAK Branches must have a permanent address, as stated in the PAK and PAK Branch Permits.
2) PAK and PAK Branch must have a building or part of a building that can store medical device products according to their designation.

3) The building must be able to protect the product from contamination, damage, including protection from excessive heat or direct exposure to sunlight, as well as animals that are vectors of diseases such as rats, birds or insects and nuisance plants such as fungi.

4) The building must have adequate security to prevent illegal access and the occurrence of danger due to improper placement of goods.

5) PAK and PAK Branches must have reception and delivery rooms designed in such a way as to prevent product mixing.

6) The receiving room should be designed in such a way as to allow cleaning of the container/place of the product received prior to storage.

7) Storage space must be adequate so as to maintain product quality and have adequate lighting and ventilation. The storage space should be equipped with rack and pallet facilities to make it easier to organize and increase space efficiency.

8) Electrical installation must be in good condition.
9) The storage room must have a product storage system that facilitates the process of taking goods.
10) All buildings must be equipped with fire extinguishers, such as fire tubes (according to the type of goods stored), *hydrants* or *sprinklers.* Fire extinguishers should be clearly visible, unobstructed by product stored in storage areas, and should be located as close as possible to exits from the building.

11) *Forklifts* and other warehouse equipment with an electric drive/battery source can be used in the warehouse.

12) *Forklifts* and other warehouse equipment with gasoline, diesel, gas propulsion sources, must not be operated in the warehouse because they can cause contamination from fuel and smoke.

13) The trolley used in the warehouse must not have sharp parts or other dangerous parts that can damage the products in the warehouse.

14) For PAK and PAK Branches that distribute electromedical medical device products and in vitro diagnostic products must have a *workshop/ workshop* facility (own or in collaboration with other companies and/or related official workshops).

b. Cleanliness

1) Storage room must be dry, clean, free of waste/garbage and dust. The written sanitation program should state the period and method used to clean the room.

2) No eating, drinking, spitting, and smoking in storage space.
3) The toilet/sink must be separated from the storage room and must be kept clean.
4) Standard operating procedures for hygiene must be available.
5) Records of cleaning activities must be maintained.

c. Pest Control

1) The storage room must be designed and equipped with equipment to prevent the entry of insects, rodents, and other nuisance animals and fungi.
2) A pest control program must be in place.
3) Records of pest control activities must be maintained.

4. Inventory Storage and Handling

a. General requirements

1) PAK and PAK Branches may only distribute products that already have a distribution permit.
2) PAK and PAK Branches can only distribute products according to the group of products that are permitted to be distributed (stated on the PAK Permit and PAK Branch).
3) PAK and PAK Branches may only distribute products from sources that can be accounted for under the provisions of laws and regulations.

4) PAK and PAK Branch must provide documents that relevant.

b. Goods receipt

1) PAK and PAK Branches must have standard operating procedures to ensure that the medical devices received are in accordance with the specified requirements.
2) Each product receipt must be checked for conformity with the order letter, including the customer's address, product name, physical condition of the product, distribution permit number, expiration date, number of products, batch number or serial number, and type and verified with the information on the label.
3) Products that are physically damaged must be separated from products received in good condition.
4) Problematic containers/packaging must be carefully inspected for damage or contamination. If found damaged or contaminated, the product is quarantined or separated for further inspection.

5) Records of receipts must be maintained. The record includes a description of the product, quality, supplier, assigned batch number and a receipt between the sender and recipient of the product.

6) Security measures must be taken in order to ensure that *damaged/ rejected* products cannot be used and must be stored separately from other products pending destruction or return to suppliers. Such measures shall be sufficient to prevent the use or disposal of the *damaged/ rejected product.*

c. calibration

1) PAK and PAK Branch must ensure that the equipment used to guarantee the storage and distribution of medical devices has been calibrated or verified against standards with national/international standards, within a certain period of time or before being used.

2) PAK and PAK Branch must maintain instructions use and maintenance activities.
3) Records of calibration and maintenance services must be maintained.

d. Storage

1) Storage Condition
a) Adequate storage facilities should be provided to ensure the product is properly stored.
b) Products should not be stacked directly on the floor, because it can cause the product/packaging to become damp and reduce safety, quality and benefits.
The maximum stack stated on each package must be adhered to.
c) Pallets/shelves must be well cared for and kept in clean condition.
d) The storage room must be safe from the possibility of mixing between eligible and unsold products.

e) There must be a space/area designed to:
- salable products;
- quarantine products *(damaged/ rejected);*
- recalled products and products return/return;
- expired products.

f) There must be a standard operating procedure for the prevention of spills or damage, microorganism contamination, and cross-contamination.

g) Appropriate storage space should be available for hazardous and sensitive materials such as flammable liquids and solids, pressurized gases, toxic materials and products containing radiation.

h) Products requiring special conditions (such as temperature and/or humidity for: sterile products) should be placed in rooms equipped with equipment to create the desired conditions.

i) Rooms with controlled storage conditions must be monitored and recorded regularly, measured at certain time intervals that can show maximum and minimum temperatures for a day, and recorded at least 2 (two) times per day. If controlled conditions are not created, it is necessary to take appropriate action against the room, equipment, and/or product. If needed, measurement

humidity is also carried out.

j) The controlled temperature must be expressed quantitatively. If the storage temperature is not stated quantitatively or stated based on the label on the product, the following instructions apply:

- *Freezer* means temperature controlled thermostatic between -20°C and -10°C
- *Refrigerator* means temperature controlled thermostatically between 2°C and 8°C
- *Cold place* means the temperature does not exceed 8°C
- *Cool place* means temperature between 8°C and 15°C
- *Room temperature* means the temperature is between 15°C and 30°C
- *Warm* means the temperature is between 30°C and 40°C
- *Excessive heat* - temperature above 40°C
- *Do not store over* 30°C means the temperature is between 2°C and 30°C
- *Do not store over* 25°C means the temperature is between 2°C and 25°C
- *Do not store over* 15°C means the temperature is between 2°C and 15°C

- *Do not store over* 8°C means the temperature is between 2°C and 8°C
- *Do not store below* 8°C means the temperature is between 8°C and 25°C
- *Protect from moisture* means the relative humidity should not be more than 60% under normal storage conditions, for products that must be protected from moisture.

- *Protect from light* means for products that must be protected from light.

k) Temperature sensors and monitors are recommended to be placed in spaces where the temperature fluctuates the most, for example in front of doors for entry and exit.

l) Equipment used to measure and monitor temperature and humidity must be properly maintained and calibrated. The calibration results must be recorded and stored.

m) Records of storage activities shall be maintained.

2) Inventory Rotation

a) There must be standard operating procedures for inventory rotation activities.

b) Separate products that have expired or are past their useful life from products that are still suitable for use, and are clearly labeled "products not for sale" or other similar terms.

c) PAK and PAK Branches must ensure that the products that expire first are sold and/or distributed first *(First Expire First Out/ FEFO).* If the expiration date is not stated, then the product that arrives first must be sold and/or distributed first *(First In First Out/ FIFO).*

d) Periodic adjustments to the amount of inventory *(stock take/ stock take/ cycle count)* must be made by comparing the number of physical and recorded inventories.

e) Records of inventory turnover activities shall be maintained.

e. Delivery and Delivery to Consumers

1) There must be standard operating procedures regarding the delivery and delivery of products to consumers.
2) The process of delivery and delivery must not affect the safety, quality and usefulness of the product.
3) PAK and PAK Branches must ensure that the products sent have clear and easy-to-read markings, including product name, distribution permit number, type, batch number or serial number, name and address of the manufacturer, as well as the name and address of the distributor.
4) Provisions regarding safety, storage conditions and protection of product quality during shipping must be included and informed to consumers.
5) Products that require controlled storage temperatures must be handled in a special way. For products that require dry ice *(dry ice)* at the time of delivery, the product must not be in contact with dry ice because it can cause the product to freeze.

   Use tools to monitor temperature during shipping. Records of the results of the temperature monitor must be reviewed and maintained.

6) The means of transportation used must be adapted to the size and condition of the product being transported, and in a well-maintained condition, and may not be used as a product storage area. The means of transportation must be inspected before transporting the product, to ensure that there is no damage, dirt or leakage.

7) Records of delivery activities must be maintained.

f. Installation and Service

1) PAK and PAK Branch must determine the qualifications for installation and maintenance of appropriate installations and have inspection instructions for products that require installation requirements, if necessary test procedures.

2) PAK and PAK Branch must ensure the necessary installation and testing in accordance with the manufacturer's instructions and installation procedures. The PAK shall maintain records of installation and procurement, including test results to demonstrate proper and satisfactory installation.

5. Product *Traceability (Traceability)*
   a. PAK and PAK Branches must maintain up-to-date records that facilitate traceability of the distributed products, including consumer name, manufacturer name, batch number or serial number, type, quantity, and distribution permit number.
   b. Records must be maintained for a certain period, in accordance with the useful life of the tool determined by the manufacturer, but not less than 2 (two) years.
   c. A tracking system down to the patient level should be established for special medical devices, such as mechanical heart valves, implantable pacemakers, implantable defibrillators, cardiac stents, implantable ventricular support systems, implantable drug infusion systems, and so on.
   d. If tracing is not possible down to the patient level, a traceability system is applied down to the user's facility. Tracing records at least include the date the medical device was implanted in the patient and the date the medical device was used or removed/removed from the patient's body.

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   e. Search results must be reported to the relevant agency authorized.
   f. Tracking records must be maintained.

6. Complaint Handling
   a. PAK and PAK Branches must have standard operating procedures in handling product complaints.
   b. PAK and PAK Branches must have a mechanism for collecting comments and complaints from users and the public.
   c. Complaint handling procedures ensure that complaints received will be investigated and followed up. Corrective action must be taken immediately to prevent the recurrence of the complaint.

   d. Personnel with the authority to handle complaints and carry out investigations should be appointed. All investigations must be documented in writing.
   e. If a defective product is found in one batch, the possibility of damage to another batch must be considered.

   f. Investigations should take into account the conditions and the environment in which the product is distributed, stored and used.
   g. The investigative report must be clearly stated covering all corrective and preventive actions. This report includes, among other things: the date when the damage occurred, the number of products, a description of the damage, how the damage occurred.
   h. Records of complaints, investigations and follow-up should be maintained.

7. Field *Safety Corrective Action (FSCA)*

   a. PAK and PAK Branches must have standard operating procedures for corrective action.
   b. PAK and PAK Branches assign responsibility for planning, implementing, and reporting corrective actions.
   c. PAK and PAK Branch establish product recall procedures *(recall)* after coordinating with producers. If a decision is made to recall the product, a recall notification must be made.

   d. PAK and PAK Branches must report the corrective action plan to the authorized agency.
   e. PAK and PAK Branches must inform corrective actions to consumers who have received the product, according to their level of importance.

   f. Records of repair activities shall be maintained.

8. Return/Return of Medical Devices
   a. There must be standard operating procedures for handling returned products.
   b. Returned products include recalled products, defective products, “complaint products”, expired products, and products returned due to administrative errors.
   c. Returned products must be stored separately from other products to prevent redistribution until a follow-up decision is reached.
   d. Returned products caused by administrative errors can be transferred to salable products according to procedures. There must be a record of the transfer of product status and responsible personnel and be placed in accordance with the FEFO system or FIFO system.
   e. Relevant records of returned products shall be maintained.

9. Destruction of Medical Devices
   a. There must be standard operating procedures regarding product destruction.
   b. Destruction is carried out on medical devices that:
      1) produced without meeting the applicable requirements;
      2) has expired;
      3) does not meet the requirements for use in health services or the interests of science and technology; and/or
      4) the distribution permit is revoked.
   c. Products to be destroyed that have not been sent to the disposal site must be placed separately and clearly identified so as not to mix with salable products and prevent accidental sales.
   d. Extermination activities must pay attention to the following:
      1) the safety of the personnel carrying out the destruction;
      2) the possibility of misuse of the product/packaging;
      3) minimize the impact on the environment; and 4) legislation regarding disposal waste.
   e. Destruction of medical devices must be reported to the competent authority by attaching the Minutes of Destruction.
   f. The Minutes of Destruction of Medical Devices must be signed by the head of the company, the technical person in charge, and witnesses, and at least include:

1) the time and place for the destruction of the equipment health;
2) the number and types of medical devices;
3) the technical person in charge of implementing the destruction of tools health;
4) witnesses in the implementation of the destruction of medical devices.

g. Records of culling activities shall be maintained.

10. Illegal and Unqualified Medical Devices (TMS)
a. Illegal products and TMS found in the distribution network must be physically separated from other products.
The product must be clearly labeled “Illegal Products and TMS” or other similar words.
b. PAK must report the discovery of Illegal products and TMS to the authorized agency and inform the distribution permit holder.

11. Internal Audit
a. PAK and PAK Branches must conduct periodic internal audits as planned, to monitor compliance with CDAKB.

b. PAK and PAK Branches must have standard operating procedures regarding internal audit which include responsibilities, requirements, planning, and reporting as well as maintenance of audit results.

c. PAK and PAK Branch shall take action to eliminate detected nonconformities and their causes without delay.

d. Records of internal audit activities shall be maintained.

12. Management Studies
PAK and PAK Branches must conduct periodic reviews of the quality management system according to the plan, to ensure its suitability, adequacy, and sustainability. effectiveness by

a. Input for study
Inputs to the management review include:
1) audit results;
2) feedback from consumers;
3) process performance and suitability of medical devices;
4) status of corrective action and preventive action;
5) follow-up from previous management studies;

6) changes that may affect the quality management system;

7) recommendations for improvement; and 8)
statutory requirements.

b. The output of the study
The outputs of the management review should include:
1) decisions and actions related to improving the effectiveness of the quality management system and its processes;
2) development of medical devices related to consumer requirements; and

3) resource requirements.

13. Third Party Activities *(Outsourcing Activity)*
a. PAK and PAK Branches must be able to control the activities carried out by third parties in accordance with applicable regulations.
These activities must be agreed upon in a written contract.
b. PAK and PAK Branch must ensure the type of control exercised to third parties.

c. PAK and PAK Branches must ensure that the activities
carried out by a third party as part of the PAK facility audit system.

d. PAK and PAK Branch can determine the activities to be
handed over to third parties as needed, except for storage activities.

MINISTER OF HEALTH
REPUBLIC OF INDONESIA,

signed

MBOI'S NAFSIAH