! Kode Etik Kegiatan Usaha Bidang Alat Kesehatan dan Laboratorium di Indonesia (Gakeslab)
The Medical and Laboratory Appliance Business Activities Indonesia Code of Ethics (Gakeslab/Association of Medical and Laboratory Appliance Companies)

Gakeslab Indonesia Code of Ethics

Chapter – I

Vision and Mission of the Organization

Vision:

- To make Gakeslab Indonesia the only Medical, Laboratory Appliance and Reagents Organization that is United and Harmonious, with a Good Reputation locally and internationally, as the best Partner for the Stakeholders in quality Health Services.

Mission:

- To encourage the Members of Gakeslab Indonesia to be more Professional and Self-reliant in the manufacture and/or distribution of Medical and Laboratory appliances, and of high-quality, safe, and beneficial Reagents, and to provide good high-value services and support to guarantee customer satisfaction (Government, the Private Sector, Foreign Countries)
- To engage in a partnership with the Government, specifically with the Ministry of Health, in the Planning and Outreach of the Regulations as well as the Supervision and Development of Companies, and to support the vision of the Health Department (a Just and Independent Community), i.e.:
    - For the people
    - Inclusive
    - Responsive to being honest and fair
    - Transparent

Introduction.

1. Whereas business activities in the field of Medical and Laboratory Appliances in Indonesia are business activities aimed at making a positive contribution to the continuing development of the Indonesian economy that has an impact on the development of the well-being of the broader community.

2. Good and continuing improvement of the community's well-being is the realization of the efforts of the Indonesian people to comply with the good and proper rules of life that are based on the principles of Pancasila.

3. The profession of Medical and Laboratory Appliance product entrepreneur is a noble and good profession which must be continuously developed and maintained so that it can bring about good management based on the implementation of the principles of good corporate governance.

4. Business activities in the field of Medical and Laboratory Appliances are an important and integral part of the total services and development of community health. Therefore, Medical and Laboratory Appliances play a strategic role in the establishment of a healthy community. A healthy community is the Pillar of the resilience of the Nation and State.

5. The skills of entrepreneurs engaged in the field of Medical and Laboratory Appliances need to be continuously fostered and developed. The objective of developing this competence is to ensure that Medical and Laboratory Appliance entrepreneurs embody the nature of a business that upholds morality and business ethics. As a result, a business climate that prioritizes well-being among entrepreneurs will develop, and eventually they will be capable of being good role models for the community.

6. Based on the above principals and driven by the noble wish to take part in making the Nation and State prosperous, also driven by togetherness in brotherhood, sincerity, unity and integrity among Medical and Laboratory Appliance Entrepreneurs, THIS MEDICAL AND LABORATORY APPLIANCE BUSINESS CODE OF ETHICS IS ESTABLISHED. Furthermore, this Code of Ethics shall become a guide, compass and framework for all activities in the Medical and Laboratory Appliances business entrepreneur efforts in their daily activities, in all of their activities and their existence.

CHAPTER II

DEFINITION OF THE ASSOCIATION OF MEDICAL AND LABORATORY COMPANY CODE OF ETHICS (GAKESLAB).

The Gakeslab Indonesia Code of Ethics represents the principles of a complete way of life for the organization and for all its members in conducting their daily activities in doing business and in interacting with their business partners based on the principles of good values, just humanitarianism, and the implementation of good corporate governance principles.

CHAPTER III

OBJECTIVE & SCOPE

Article - 1
Objective.

a. The objective of the implementation of the Medical and Laboratory Appliance business CODE OF ETHICS is to develop a business culture in the field of Medical and Laboratory Appliances that is professional, steadfast, and capable of being the host in one's own country.

b. To build a spirit of togetherness among entrepreneurs in similar fields based on mutual appreciation, respect, and togetherness among the members of the organization. These attributes are based on upholding moral values and business ethics so that just business practices will be established and remain dynamic in any situation.

c. To realize continuous business growth in the field of Medical and Laboratory Appliances in the Unitary State of the Republic of Indonesia (NKRI) that contributes actively to the development of the overall health of the community by upholding the values of professionalism with a high level of integrity.

d. To be able to place itself and its organization in an integrated whole and to be able to be an equal partner with the government in bringing about the steadfastness of the Nation and State through dynamic and up-to-date movements and activities in Medical and Laboratory Appliances. To comply with the principles and applicable regulations and always be firm in upholding the principles of truth and integrity.

e. To make Medical and Laboratory Appliance commercial entrepreneurs both personally and as an organization capable of taking their place as the pioneers of good conduct in running their businesses by complying with the principles of good corporate governance and being able to be role models for the broader community.

Article 2
Scope

The GAKESLAB INDONESIA Code of Ethics covers all of the activities of the Medical and Laboratory Appliance business divided into the following fields of business:

a. Manufacture of Medical and Laboratory Appliances.

b. Commerce, agencies and distribution of Medical and Laboratory Appliances.

c. Services, calibration, and maintenance of Medical and Laboratory Appliances

d. Promotion of Medical and Laboratory Equipment.

e. Personnel competency training and certification of Medical and Laboratory Appliance business organizations.

f. Medical and Laboratory Appliance procurement planning services at health facilities.

CHAPTER II
CODE OF ETHICS

Article - 1
Code of Ethics for Manufacturing

1. Manufacturing business that takes the form of Medical Appliance manufacture in Indonesia is a good and noble business. Therefore, every Medical and Laboratory Appliance manufacturing business must be oriented to the welfare of the Indonesian people and always prioritize the quality of products that can contribute to the efforts to heal patients by continuing to prioritize patient safety.

2. The conduct of the Medical and Laboratory Appliance manufacturing business in Indonesia must comply with applicable regulations in accordance with other laws and regulations of the government that regulate this business and the manufacturing process. The manufacture of Medical and Laboratory Appliances as well as Diagnostic Reagents are businesses that must be good and correct with regard to the law, which should always be updated in compliance with applicable laws and regulations

3. The Medical and Laboratory Appliance industry must be capable of being the corner stone of economic growth for communities in the vicinity of industrial sites. Therefore, the medical and laboratory appliance industry in Indonesia must endeavor to grow and develop continuously together with the communities in the vicinity of which the industry is located. Efforts must be made for a growth barometer in such a way that growth can be monitored from time to time.

4. The Medical and Laboratory Appliance industry is required to take into account the aspect of environmental contamination safety. Therefore, all Medical and Laboratory Appliance industries must comply with the applicable laws on environmental impact assessment and prioritize the implementation of a "Green Industrial system" in its industrial processes, operational processes and also its product results.

5. Fellow entrepreneurs in the Medical and Laboratory Appliance industry must cooperate in efforts to respond to the demands of domestic health appliance needs in order to establish national resilience by the strengthening of this Medical and Laboratory Appliance industry.

6. Any issues that arise between the entrepreneurs in this industry shall first be settled amicably and through consensus and by consistently upholding the prevailing high values and ethics of commerce and industry.

7. In product development, efforts shall always be oriented toward the efforts and actions carried out by the HCP by continuously prioritizing efforts to heal patients. The forms of cooperation carried out shall be transparent and clear so that any negative impact arising from this cooperation can be avoided.

8. It is forbidden for Industry actors to establish a research and development centre together with the HCP or other industries in that such research and industry must be in compliance with prevailing standards of medication. Research efforts shall be based on truth, honesty, integrity, and earnestness in the efforts to heal the patients and consistently take into account the importance of patient safety. The prevailing ethics of human research and local ethics must be followed properly and correctly. All types of product development research shall be integrated and reported to the regulator/government for their reference and for the acceleration of the process. Research results shall prioritize the interests of the community so that the results of their future findings will really be useful to the broader community for their purchase and use.

9. The actors in the Medical and Laboratory Appliance industry shall be responsible for the functions, benefits and performance of their products in accordance with the objectives of developing and manufacturing such products. These responsibilities shall be continual, starting from when the product is released to the market and is used by HCP until the retirement of such appliance has been reached. During its usable life, the manufacturer concerned is required to conduct built-in monitoring in the form of close cooperation with the supervisory officer of Medical and Laboratory Appliances from the authorized agency appointed by the government. The cooperation that has been established should be pure cooperation that prioritizes efforts for patient cure and safety by upholding high moral ethics, based on a high degree of humanitarianism and good and correct integrity. Compliance with the prevailing laws and regulation covering this field of cooperation must be carried out without exception.

10. Product quality is a priority for the actors in the Medical and Laboratory Appliance industry. This quality should be maintained from when the product is released from the factory warehouse until such time as the product service time has been completed. Therefore, management of the product during transportation, usage and until it is retired from use are the responsibilities of the manufacturer. The producer must offer education in all relevant aspects through training, public communication, and product brochures.

Therefore, these Medical and Laboratory Appliance products will really make a maximum contribution towards total efforts to cure patients in need of such products.

11. Training programs on the use, utilization, maintenance, and destruction after completion the of usage time are the responsibilities of the health community. The actors in the health appliance industry are required to participate in such efforts. These training efforts really need to be conducted as good efforts, with integrity, and are aimed at bringing about the maximum performance of such products and of patient safety. Actions that harm the patient and only benefit industry actors and HCP are prohibited. Preventive measures must be undertaken through the entrepreneur code of conduct for themselves and for the HCP that use the product.

12. Local manufacture of Medical and Laboratory Appliances must continually carry out self-improvement so that it is capable of becoming an industry with a high level of competitiveness both on the local market and on the international market. This competitiveness must be realized by the adoption of a quality ranking of the products manufactured and also of their manufacturing facilities based on applicable certification qualifications. Therefore, industry entrepreneurs must join with similar business actors or others in an effort to build up a continual level of ability.

Article - 2
Trading business and Agency Code of Ethics.

1. The Medical and Laboratory Appliance product commercial business in Indonesia will continue to grow and develop in line with the need for Medical and Laboratory Appliances in supporting good health services for the entire Indonesian community. Therefore, Medical and Laboratory Appliance product entrepreneurs are required to maintain and strive to keep trade in these products among the entrepreneurs domiciled in Indonesia.

2. The commercial practices carried out in medical and laboratory appliance businesses will be guided by mutually beneficial commercial practices between the entrepreneurs (Stakeholders), product users, and patients as the objects of this business. In running the business, the commercial business entrepreneurs of these products must always prioritize patient safety, product quality, product performance, and warranties in compliance with applicable provisions.

3. These mutually beneficial practices should be carried out periodically in a consistent way, and always be up-dated in compliance with the prevailing regulations and in accordance with situations and conditions in line with developing changes in technology and in systems of therapy.

4. Medical and laboratory appliance commercial entrepreneurs are responsible for the quality and benefits of the Medical and Laboratory Appliances being traded/manufactured during transportation, installation, and use by patients including the maintenance and

storage process, even up until their future destruction when their useful period has been completed. The evidence of such responsibilities shall be realized by monitoring the activity of the products through the procurement of a database of the products that continue to be monitored.

5. Medical and Laboratory Appliance commercial business entrepreneurs shall be responsible directly or indirectly for training on the utilization of the products being sold. The impact and consequences of the utilization of medical and laboratory appliances beyond required regulations provided in the training are beyond the responsibility of the entrepreneurs of the product concerned.

6. Training in the form of the maintenance of the appliances and emergency repairs are also part of the responsibilities of medical and laboratory appliance entrepreneurs so that patient safety will be the top priority in the utilization of such health and laboratory appliances.

7. Medical and laboratory appliance commercial entrepreneurs must go along with the principles of conducting research on the utilization and development of new indications of the relevant product. Work on this research must be reported to the authorized agency and must comply with formally prescribed research standards. The research must be conducted transparently and it must be done by accountable experts so that the results will actually be an effort to improve the provision of health services to the community.

8. Medical and Laboratory Appliance commercial entrepreneurs shall be responsible for the engineering design and commissioning process of the product being traded/accountable for, so that such products can result in good performance as intended.

9. The entrepreneurs shall be responsible for the Medical and Laboratory Appliance product warranty as promised. The provision of competent engineering service officers and a maintenance schedule for the appliances shall be the guidelines to be followed by the users of the appliances and the entrepreneurs. Therefore, the performance of such appliances will not be used as something negative for the patients where the Medical and Laboratory Appliances are used.

10. Medical and laboratory appliance entrepreneurs are required to comply with the applicable commercial regulations in the Unitary State of Republic of Indonesia (NKRI) whether with regard to the regulations stipulating their commercial aspects, their other legal aspects, and their sustainability.

11. In the event a company ceases to do business, the entrepreneur is required to turn over the customer database to the successors of the business or to the authorities so that the Medical and Laboratory Appliances installed on the customer's premises will continue to be maintained as required.

12. Medical and Laboratory Appliance entrepreneurs shall be responsible for supplying spare parts for the products traded in accordance with the term of the guarantee provided and the function of such appliance within at least 5 (five) years after such appliance is officially used.

Article 3
Commerce & Industry Code of Ethics
Commercial practices and product distribution.

1. In trading Medical and Laboratory Appliance products, the commercial ethics procedures that apply within the territory of the NKRI shall be the primary guidelines.

2. In accordance with prevailing regulations, every member of Gakeslab will automatically become a member of the Indonesian Chamber of Commerce and Industry. Therefore, the code of ethics in Kadin (Indonesian Chamber of Commerce and Industry) shall also be the guidelines for conducting their activities.

3. The commercial ethics referred to mean that the application of good Corporate Governance standards as required must be properly and consistently conducted and applied.

4. Their commercial processes should be well performed and regularly documented. Therefore, Medical and Laboratory Appliance industry entrepreneurs as members of Gakeslab will become a company that can be held accountable and is trustworthy.

5. In running their business activities, Medical and Laboratory Appliance industry entrepreneurs shall comply with prevailing regulations including commercial practice regulations. In this matter, the publication of prices for the public is absolutely essential. Price mark-ups and offering unreasonable discounts and violations of the laws and regulations stipulated by the Government of the Republic of Indonesia are prohibited. Therefore, commercial activities that lead to the possibility of corruption, collusion, and nepotism must be avoided and will not be possible.

6. In business competition between fellow members in conducting their activities, the norms and ethics of mutual respect and fairness and the characteristics of brotherhood should be established so as not to put each other out of business.

7. In meeting the government's needs in the field of Medical and Laboratory Appliances, Medical and Laboratory Appliance business entrepreneurs are required to comply with prevailing regulations without there having to be any unethical intervention and violations of the prevailing regulations. Corrective actions on the process of carrying out government purchases of Medical and Laboratory Appliances should be carried out professionally and be organized by staying within the corridors of the Gakeslab Indonesia organization.

8. In the process of daily business activities anywhere and at any time within the territory of the NKRI, the members of Gakeslab shall be prohibited from using any endorsements in the form of recommendations or supporting letters and similar things that originate outside the scope of the Medical and Laboratory Appliance business and are in violation of their business arrangements as well as of their business ethics.

Article 4
Medical and Laboratory Appliance Promotions

1. Definition

- **a.** Promotional activities are business activities conducted intentionally to communicate the product being traded to the public or target customer so that they will form an opinion or a positive image of such product, where eventually the public or target customer will make the decision to buy the product being traded.
- **b.** The said promotional activity may be in a static or live form in any form of activity including direct or indirect electronic activity.

2. Promotional activities that are ethical and comply with business ethics are legal and permitted activities and are also protected by the laws and regulation applicable in the NKRI.

3. The promotional activities conducted by Medical and Laboratory Appliance Industry commercial entrepreneurs shall be guided by promotional activities based on the prevailing Regulations of the Government, in this instance the Ministry of Health.

4. The benefits of a product that are still being investigated or are being researched shall not be allowed to be revealed or included in promotional activities. Only real benefits that have been officially declared and included in the registration documents approved by the regulator are permitted to be used as part of promotional activities.

5. All Medical and Laboratory Appliance product promotional activities must be conducted solely for the purpose of product benefits aimed at the efforts of patient recovery, patient safety, and its users. Promotional activities containing business elements in the form of commissions, profit sharing and the like are strictly prohibited.

6. Organizing a promotional activity that is realized in a form of an Advertising Gift or gimmicks in any form whatsoever that are not related to the product being promoted or related to the proper and true instructions for the use of such product are not permitted.

7. Promotional activities in the form of a scientific Seminar for HCP are permissible if they are aimed at improving skills and capabilities in utilizing them and are also not directly related to sales transactions.

8. Promotional activities in the form of a sponsoring fee for individual/personal purposes to the HCP are prohibited. Sponsorships can only be given to the institutions or organizations that organize such activities. Sponsorships are only permitted to be given to an institution or legal aspect without relating it to an individual HCP or sales transaction that will be or has already been done.

9. Donations given to an Institution or the community by the manufacturer or a commercial business entrepreneur can only be permitted for the purpose of helping the community, the nature of which is to reduce any burden on the community. This activity is not permitted if it relates to a sales transaction of the product under its agency or what it manufactured.
10. In the event that there are any other activities that are CSR activity in nature, it is prohibited if such activities relate to a sales transaction or to the promotion of the Medical and Laboratory Appliance products under its agency or what it manufactured.

CHAPTER III
CODE OF ETHICS VIOLATIONS

Article - 1
Types of Violations

1. Definition of violation
- **a.** Violation of the code of ethics means performing an action intentionally or unintentionally that violates or is contrary to the ethical procedures of any activities related to commerce or the medical appliance industry within the territory of the NKRI.
- **b.** The violation levels referred to in Chapter – III Article – 1 shall be described in detail on a separate sheet that is an integral part of this code of ethics.
- **c.** The types and provisions of the violations of this code of ethics shall be evaluated and revised continuously in accordance with business developments and prevailing laws and regulations as well as in compliance with the pre-requisites of regional or international harmonization.

Article - 2
Investigation of a problem.

1. Violations of the code of ethics found by the official management or officers of the Ministry of Heath or reported by the community shall be observed and cross-examined by the appointed Code of Ethics Committee.

2. The results of the investigation of a problem shall put on the agenda of a committee meeting.

3. Furthermore, the code of ethics board committee shall decide what measures are to be taken against the member who violated the code of ethics.

Article - 3

Types of Action Taken Against Code of Ethics Violations

1. Actions/punishments to be taken by the organization against a member of GAKESLAB INDONESIA who violated the Code of Ethics shall be determined after being decided by a code of ethics board hearing.

2. Actions to be taken by the organization shall be committed in stages according to the types of violation and its gradations.

3. Violations committed by a member along with the action to be taken by the organization shall be determined as contained in the attachment herein, which forms an integral part of these code of ethics regulations.

Article 4
Defense

1. Every member subject to sanctions shall be given the opportunity to conduct his/her defense through a special code of ethics hearing on the matter.
2. The code of ethics hearing levels shall be regulated as follows:
    a. The first hearing shall only be attended by the code of ethics board.
    b. The second hearing shall be attended by the code of ethics board and by the members of the head office executive board.
    c. The highest hearing shall be a plenary hearing of the members where the highest decisions of the organization are determined.
3. A special code of ethics hearing can be held at the request of a member at which there will be a code of ethics judge and also a registrar along with the defense team.
4. A decision on the results of the code of ethics hearing shall be absolute and binding. A review shall be conducted if there is any new and reliable evidence.
5. A review hearing on the decision of the code of ethics board shall be determined at the National Congress of the organization.

CHAPTER IV
IMPLEMENTATION OF THE CODE OF ETHICS
Article 1
The appointment of Members of the Code of Ethics Board

1. Members of the Code of Ethics Board of Gakeslab Indonesia shall be elected, appointed, and dismissed by the members at the National Congress of the Organization, which is the highest board in the organization.

2. The appointment of members of the code of ethics board shall also be based on a decision in the National Congress of the Organization following the articles of association of the organization.

3. Members of the Board of Ethics shall be appointed from among the members who are entrepreneurs and/or from among other experts who understand the Medical and laboratory appliance business and who are deemed to possess the competency and credibility to perform their duties.

Article - 2

Duties, Responsibilities, and Position of the Code of Ethics Board

1. The code of ethics board has the task of bringing about the understanding and adoption of the organization's code of ethics in the business activity practices of each member of the organization as well as in the arrangements made for the organization's performance.

2. The code of ethics board is answerable to the organization that is presented periodically in the form of a regular annual report. A complete accountability report shall be submitted to the national congress of the Organization at the time said national congress is held as stipulated in the articles of association of the organization.

Article 3
Outreach and Supervision

1. The application of the Code of Ethics on Medical Appliances Business shall be regulated in rulings which are then to be outreached by the Head Office Executive Board of GAKESLAB INDONESIA, taking into consideration the provisions of this organization.

2. The outreach process shall be conducted in various ways and methods either directly or via any available electronic network system.

3. The code of ethics outreach in the regions shall be conducted simultaneously at the initiative of the head office and the regions.

4. Outreach of the organization's code of ethics to other organizations outside the Gakeslab organization shall be the responsibility of the head office management.

5. Reports on violations of the organization's code of ethics can be made by an organization member, partner organization in the field of health and the community by attaching a detailed and valid document of evidence of the violation concerned supported by other relevant representative evidence.

6. A report on the violation of the organization's code of ethics shall be addressed to the code of ethics board's head office through existing branch managers.

7. The authority to supervise the implementation of this Code of Ethics shall be conducted and implemented by the Code of Ethics Board of GAKESLAB INDONESIA.

8. The Code of Ethics Board shall prepare a system and procedures (SISDUR) for the implementation and supervision of the Medical and Laboratory Appliance business Code of Ethics.

CHAPTER V
APPROVAL

Pasal 1

Article 1

1. The code of ethics board is fully responsible for the feasibility and compliance stages up to the process of approving the organization's code of ethics.

2. The approval of Gakeslab Indonesia's code of ethics and its revisions and amendments shall be conducted in compliance with the written regulations in the articles of association and the Household budget of the organization.

3. The basis for any amendment or revision of the code of ethics is the existence of any new state laws and regulations from the government of the NKRI, the development of international harmonization, the development of existing business situations, and suggestions from the members.

4. Any amendments, revisions, and improvements to the code of ethics shall be pursuant to the applicable Code of Ethics law and Government Regulation of the NKRI.

5. Amendments and revisions of the Code of Ethics shall be conducted by an ad hoc code of ethics formulating team and formed by the board of the organization.

CHAPTER VI
CLOSING
Article 1

1. The first code of ethics organization was approved at the 5th National Congress of the Organization held in Pontianak, province of West Kalimantan on January 19 – 20, 2011.

2. As of the imposition of this Medical and Laboratory Business Code of Ethics, any existing Medical and Laboratory Business Code of Ethics and its derivatives shall no longer be in force.

Approved on:..... at the National Congress of Medical and Laboratory Businesses (Munas Gakeslab) ,,,,,,, held in:
.....on.....

Code of Ethics Board Chairman

Head of the Organization

Code of Ethics Board Members

1. ……
2. ……..
3. ……..
4. ……