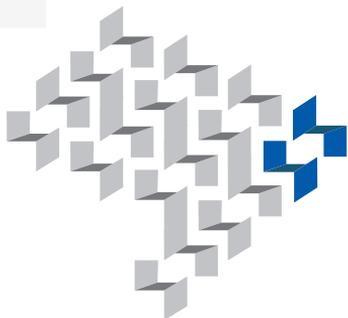


CODE OF ETHICS



abimed

Associação Brasileira dos Importadores
de Equipamentos, Produtos e
Suprimentos Médico-Hospitalares

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ABIMED CODE OF ETHICS

3rd Edition
Revised and Updated
São Paulo/ SP – 2010

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CHAPTER I – Introduction – ABIMED’s Vision and Mission and Objective of the Code of Ethics

ABIMED **envisions** becoming the most representative entity of the product sector of ADVANCED MEDICAL TECHNOLOGY in Brazil. ABIMED shall be dynamic, influential and a partner to the government and private authorities, as well as related associations. We work to improve the Brazilian medical/hospital services through the importation of equipment and quality materials at competitive prices compatible with available technology. We shall promote progressive “debureaucratization” of importation processes and systems and the reduction of technical barriers that do not fundamentally guarantee the safety and efficacy of products and services, which will favor expanding access of Health Technologies to the Brazilian Society.

ABIMED’s **mission** is to represent its Associates in defending their interests before government agencies and private entities, in Brazil or abroad, contributing with the best solutions for the healthcare system.

ABIMED’s Code of Ethics objective is to establish basic conditions of conduct that shall guide the actions of the associate companies, which are determined to limit their activities to comply with legal orders and observe technical, moral and ethical standards recognized by local, national and international societies.

>> Application of this Code of Ethics is required of all associate companies, and shall be recommended to other companies and agencies that interact with the associate companies, and is superseded by the Legislative, the Executive and the Judicial authorities.

CHAPTER II – Guidelines

The development of high technology, together with the improvement of medical equipment and existing therapies are the direct result of a collaborative process between medical device companies and Healthcare Professionals, including medical institutions.

In this sense, ABIMED recognizes that the primary objective of healthcare professionals is to offer the best possible treatment to their patients. Medical device companies also try to consider the interests of patients through the collaboration with such professionals in developing new therapies and techniques.

The collaborative relationship between associate companies and healthcare professionals is an inherent part of the success in delivering pioneering therapies to patients. This relationship

should be established taking into account the law and highest ethical standards, as well as critical and significant issues that may affect constant collaboration. This Code of Ethics establishes the structure for these relationships.

Compliance with the provisions of this Code of Ethics aims to protect the associate companies, subject to a number of existing laws, regulations and rules in Brazil, as well as in other markets, due to their origin or presence, in various places in the world. Nevertheless, this Code of Ethics also aims to protect patients and users, as well.

In addition, in order to achieve the highest standard of ethical commercial practices, the companies associated to ABIMED while performing their commercial activities shall compete openly and properly in the market, always defending and respecting free initiative and a competitive system, never performing, permitting or omitting actions that can be characterized as an act of corruption, coercion, fraud or favoritism to a certain company, to the detriment of the well-being of patients.

Quality, prices and services are attributes that should also guide the high ethical standard of commercial practices, which is the objective of ABIMED and its associates.

Any commercial and importation transaction should respect and follow all legal and fiscal requirements effective in Brazil.

In this regard, ABIMED and its associates recognize that adherence to ethical commercial practices and respect of the applicable laws is indispensable to the development of new products and therapies by medical device companies. Associate companies should encourage the adoption of ethical and socially responsible commercial practices in all interactions with Healthcare Professionals and third parties, always respecting the duty of Healthcare Professionals to independently decide which product or therapy is best for each patient.

Associate companies should never:

- >> Perform any action that could cause damage or result contrary to the interests of the public, Healthcare Professionals or patients.
- >> Refer to products and services of other companies, associated or not, with the mere intention of diminishing the goodwill of such products or services, through printed media, electronic media, their representatives or agents, directly or indirectly, explicitly or implicitly.

Under no circumstances should the associate companies use ABIMED's information for purposes contrary to the principles established in this Code of Ethics.

Four basic principles serve as a guide to the rules provided by this Code of Ethics - Separation,

Transparency, Equivalence and Documentation – forming a basis for the standards established herein, and which associate companies are expected to observe while conducting their businesses:

- >> Separation – it determines that interactions with Healthcare Professionals are not used incorrectly, in order to influence purchasing decisions or where the Healthcare Professionals become dependent on the utilization or sale of a medical device;
- >> Transparency - it refers to the assurance that the interactions between associate companies and Healthcare Professionals are clear and that they are communicated in writing to the employer of the Healthcare Professional, whenever necessary;
- >> The principle of Equivalence establishes that any remuneration paid to a Healthcare Professional, in performing any service or consultation, should be proportional to the service performed and have a fair market value; and
- >> Documentation - provides that whenever a Healthcare Professional offers assistance to any associate company, a written agreement should be entered, specifying the services to be offered and any payments to be made.

Additionally, associate companies from the United States of America also need to follow the rules established by the Foreign Corrupt Practices Act (FCPA), which apply to any U.S. legal entity, whether a company, a corporation and/or a partnership, together with its officers, directors, employees, agents and/or shareholders, including any individual or entity that operates outside of the USA.

The associate companies should ensure that any third parties that act on their behalf in any transactions or represent them before any Healthcare Professionals and patients, including, but not limited to independent commercial representatives (agents), distributors, brokers, consultants, employees, etc., comply with the highest ethical standards of commercial practices, which include the guidelines established in this Code of Ethics. Additionally, it is recommended that the obligations of third parties regarding such standards be in a written form, as a contract condition agreed to between the parties.

ABIMED suggests that all associate companies adopt this Code of Ethics in case they do not have one in place, implementing the rules established herein, as well as elaborating policies and procedures, in order to incentivize and ensure adherence of its employees and third parties to the limits established herein when interacting with Healthcare Professionals and patients.

CHAPTER III – Interaction between Associate Companies

The associate companies should maintain high standards of collaboration and mutual cooperation, whenever convenient for those involved, and practice healthy technological and commercial competition according to the association's ethical standards.

When disputing the contracting of its services and products, the associate companies should not use disparaging and unfounded references regarding their competitors with the exclusive intention of harming them, however they are permitted to warn clients about poorly formulated proposals which do not fulfill their legitimate interests.

The associate companies should combat any and every initiative that induces cartel formation. Although it is impossible to provide a complete list of antitrust rules to cover all the possible situations that could arise in an association, as a general rule that should be prudently followed in all meetings -- it is suggested that commercial topics should neither be discussed nor considered.

To avoid the most sensitive topics, discussions of the following topics in meetings and events between associate companies should be avoided:

- >> Present or future prices, including discounts, promotions and credits;
- >> List of prices or procedures for the coordination of price changes;
- >> Sales or production quotas;
- >> Allocation or division of territories or clients between manufacturers, distributors, resellers, agents, etc.;
- >> Boycotts or prohibition of access to the market, products, raw materials or information;
- >> Individual company statistics, market share, inventory or promotional practices;
- >> Commercial practices of competitors or specific consumers;
- >> Debts, commercial certificates or guarantees or terms and specific sales conditions, including topics on credit, logistics and transport; or,
- >> Any topics that can lead to commercial abuse and that exclude or control competition.

CHAPTER IV – Interaction with Government Agencies

The associate companies should act in a manner that adds value and quality to the Country's healthcare system.

The associate companies have the duty to respect and contribute so that the Codes of Ethics of Public Agencies are fulfilled, contributing to the strengthening this relationship.

The associate companies dedicate themselves, whenever necessary, to transfer technical knowledge based on the entity's activity to the Brazilian National Healthcare Surveillance Agency (ANVISA - Agência Nacional de Vigilância Sanitária), or any other government regulation authority.

In the deliberation and conduct of its relevant regulatory affairs, and with the intent of transmitting transparency in its activities, the associate companies should, whenever possible, act hand-in-hand with the Sanitary Authorities or be represented by competent third parties who are dedicated in observing the guidelines established by this Code.

The associate companies should behave as partners of ANVISA, or any other government regulatory agency, with regard to condemning bad regulatory and quality practices in the market.

The associate companies interact in various ways with regulatory authorities, e.g.: agencies that regulate authorizations of clinical studies, approve products, register products and production sites, issue construction permits, define prices and reimbursement rates, issue certificates of free sale and release certain products. In addition, some of these authorities and other government agencies carry out inspections (routine or targeted) and can visit the associate companies' site, with or without prior notice. These inspections can examine Good Clinical Practices, Good Production Practices (including Quality System Rules), fulfillment of sanitary vigilance, fair commercial practices, and compliance with competition laws, taxation, environmental impact studies, to mention a few.

No payment or other incentive can be offered or made by an associate company to alter the review, result or suspension of an inspection.

The associate companies can contract third parties to interact with these regulatory authorities on their behalf. These third parties include regulatory consultants, price and reimbursement consultants, consultants for evaluation of medical technology and clinical research organizations. Any third party contracted by an associate company to interact with government regulatory authori-

ties or inspection authorities should undergo a due diligence process to identify associated risks of interaction with the government. Every third party consultant should have a written agreement prior to undertaking any work on behalf of the associate company.

Payments and Regulatory Authorities

In a number of circumstances, the associate companies have to pay regulatory authorities (registration fees, renewal fees, etc.). Any of these payments can only be based on clearly established, published and transparent laws and regulations. The payments should be correctly documented and approved according to the company's financial procedures and can only be paid to banks in Brazil. The same rules apply to third parties who make payments on behalf of an associate company.

Hospitality

Companies associated with ABIMED, or third parties who act on its behalf, may offer gifts, presents, hospitality or entertainment to regulatory agencies according to the Code of Ethics of each entity and the relevant laws, especially the Code of Conduct for High Federal Administration, which limits the amount to R\$ 100.00, or no commercial value, among other conditions provided for therein.

Meetings and Minutes

Meetings with regulatory agencies and inspection authorities should be documented in a correct and proper manner, with minutes that identify the participants (representing the government and company, including third parties) and provide sufficient details on the topics reviewed. The minutes should be maintained according to policies for retention of records applicable to each company.

CHAPTER V – Interaction with Clients

The associate companies should clearly and precisely establish the duties and obligations of each party in the contracts entered with clients, indicating in a clear and precise manner which commercial, regulatory and good governance practices should be followed, as well as respect current laws and regulations in Brazil.

The associate companies should promote joint efforts to guarantee that their Distributors, Hos-

pitals and Healthcare Professionals provide patients with products of the same quality and safety as those originally produced.

It is the responsibility of the associate companies to disclose to their employees and any third parties who work on their behalf, the knowledge that product quality is a consumer right and is directly related to the aspects of reliability, conformity, stability and effectiveness; thus, products sold and services rendered should always adhere to these principles.

CHAPTER VI – Interaction with Suppliers

The associate companies should clearly and precisely establish the duties and obligations of each party in contracts with suppliers, together with commercial, regulatory and good governance practices to comply with current laws and regulations in the country.

Each time an associate company has to acquire raw materials, goods and/or services from any government entities, such interactions should be supported by written purchase orders. Payment for the raw materials, goods and/or services should be duly documented and approved according to the financial procedures of the company and can only be made via banks established in Brazil. Raw materials, goods and/or services should not be acquired through any undocumented exchanges or trades for goods or services.

The purchase of raw materials, goods and/or services from government entities should be conducted without favoritism, at fair market value, and never in conjunction with reciprocal purchase of goods and/or services by the same government entity or related entities. All payment documents should reference the written purchase order corresponding to the payment. Whenever possible, the government entity should provide a payment invoice or a receipt as evidence of payment.

Any third party contracted by an associate company to participate in purchases with government entities should have a written contract before executing any work on behalf of the associate company.

Associate companies can contract ex-politicians or ex-members of public administration for the provision of services e.g., to deliver a lecture or consultancy services. Associate companies should comply with rules and legal restrictions that apply to former government employees. There can be a legal restriction in contracting or employing former government employees for a certain period after their departure from government or public duties. Therefore, the associate company must ensure that such hiring be consistent with any post-government service employment restrictions. Although a written contract is not necessary for a single event, such as a lecture, written contracts

should cover more extensive services.

The following rules should always be observed when an associate company contracts third party services:

- >> Services paid for by the associate company should fulfill a legitimate and documented need of the business;
- >> Such services should be obtained from individuals who evidently have special knowledge or expertise to execute the services;
- >> Such services should be performed according to the terms of a written contract;
- >> The associate company can only pay for services as provided for the terms of the written contract;
- >> The remuneration should be at fair market value for the services rendered;
- >> The performance of services should be documented; invoices for workers should be sufficiently detailed to maintain a proper account; and,
- >> Whenever appropriate, the payments should be linked to strategic goals/objectives.

The terms and conditions of the written contracts of certain fees for service agreements should include the following contract terms:

- >> Agreement to comply with applicable local and anticorruption laws;
- >> Provision permitting contract termination by the associate company if there is any evidence that any offer, promise or payment was possibly made violating the anticorruption laws;
- >> Rules related to the payment of remuneration and financial transparency of detailed accounts that allow for proper bookkeeping; "success fees" are normally discouraged; and
- >> An agreement to cooperate in the event of controversies.

CHAPTER VII – Interaction with Healthcare Professionals

The associate companies are responsible for promoting education and training for Healthcare Professionals, as well as efficient and safe use of its products. However, this should be done together with qualified teams with appropriate experience in clinical and educational scenarios. When the training is of a practical nature, it should be carried out in medical institutions, laboratories or other appropriate facilities.

The associate companies should make sure that travel and lodging costs incurred by the Healthcare Professionals participating in the trainings are appropriate, not extravagant and compatible with market prices. Payment of transportation, food and lodging expenditures is limited to occasions inherent to the specific event and exclusively related to the invited Healthcare Professionals. It is absolutely prohibited to pay or reimburse any expenditure of family members, companions or persons invited by the Healthcare Professional.

The associate companies can sponsor flights for Healthcare Professionals, but the transport should be strictly adequate for the proposed event and compatible with the final destination.

Additionally, payment or reimbursement of expenditures related to recreational trips and/or activities during educational events is prohibited.

Any entertainment for the Healthcare Professionals or Professionals of the Healthcare field should be modest and secondary in relation to the main scientific event.

Adult entertainment will never be appropriate and the associate companies are not allowed to offer such entertainment to the Healthcare Professionals.

The associate companies can provide resources for legitimate and independent conferences for educational purposes, for clinical research and donations to charitable entities.

When the associate companies choose to enter consultancy agreements with Healthcare Professionals, such agreements should reflect the conditions of interaction in a clear and precise manner and should be well-documented regarding the services offered, with fair payment conditions compatible with market practices and duly signed by the parties.

Dining with Healthcare Professionals should be consistent with the exchange of scientific, educational or business information.

The supply of gifts and presents to Healthcare Professionals by the associate companies should have a modest cost and should not be personal items, but items appropriate for an educational function or to benefit patients or Healthcare Professionals in the practice of their profession. This practice should, however, not be used to induce a preference for the company's products by Healthcare Professionals.

Under no circumstances, are associate companies permitted to offer cash or any equivalent, directly or indirectly, to Healthcare Professionals. The associate companies cannot supply

items that can be used by Healthcare Professionals (or their family members, office colleagues or friends) that have no educational purpose or no relation to patients (for example, but not limited to, a DVD player or an MP3 player).

The associate companies are permitted to offer gifts and presents to Healthcare Professionals, while respecting the following conditions:

Offering gifts

- i) They should be objects of visible promotional character, always identified by a trade name determined by the company;
- ii) They should be items related to medical practice or administrative routine in a doctor's consulting office, clinics, hospitals; and
- iii) They should be objects which maximum individual value does not exceed 1/3 (one third) of the minimum national salary on the date of purchase.

Offering presents

- i) They should only be offered on an occasional basis, such as national or professional commemorative dates and cannot exceed a limit of four (4) times a year;
- ii) They should be properly registered in internal books of the associate companies;
- iii) They should be within the value limit corresponding to each type of present as follows:
 - a) With regard to items related to medical practice, such as: anatomy models, books, journals, (not including subscriptions) and other scientific publications, independently of the format or media – two (2) times the minimum national salary at the date of purchase;
 - b) With regard to items related to medical practice – half (1/2) the minimum national salary at the date of purchase.

When the Healthcare Professional is linked to public authorities or officials, the limits as provided by current federal, state or municipal laws shall apply to this employee and/or public agency to which he/she is associated.

For top federal workers, the limit of the value for presents is a hundred Brazilian Reais (R\$ 100.00) per year, regardless of the quantity. Above this value, no gift or present can be offered.

A – Product training and new techniques

The associate companies can develop training activities always seeking efficient and safe use of products and aiming to educate and train Healthcare Professionals.

Such trainings can be offered to people and/or qualified experienced teams in appropriate places, such as clinics, laboratories, educational institutions or higher education institutions, including the associate companies' sites, whenever possible. When training is of a practical nature, it should be conducted in medical institutions, laboratories or other appropriate facilities.

The associate companies can make payments for travel costs that Healthcare Professionals incur to attend trainings, always observing the principles of this chapter.

The associate companies cannot make payments and/or assume, in any way, the costs incurred by guests of Healthcare Professionals, considering that it is the sole responsibility of the Healthcare Professionals to ensure that the necessary measures are undertaken so that their guests can accompany them.

Payment for social activities and entertainment is not allowed.

B – Support to Educational Congress Events Organized by Third Parties

The associate companies can supply resources for Events and Congresses organized by third parties provided that they are legitimate, independent and have an educational purpose for clinical research and/or donations to charitable organizations.

These Events and Congresses are generally organized by regional or national medical Associations and/or Societies, with a specific specialty, seeking to impart knowledge among the Healthcare Professionals. The associate companies can sponsor these Events and Congresses in a number of ways, such as:

>> **Sponsorship to Health Professionals** – Whenever allowed by applicable laws and rules, (including the code of professional conduct, etc.), the associate companies can financially support Healthcare Professionals so that they can attend Events and Congresses organized by third parties as defined by this chapter, but they should ensure that the appropriate travel and accommodation costs are compatible with market prices. The associate companies cannot make payments or assume the costs incurred by persons invited

by the Healthcare Professionals, considering that it is the sole responsibility of the Healthcare Professionals to ensure that necessary measures are undertaken so that their guests can accompany them. This support should never be linked with the purchase of the associate company products by the institution or based on a past or future use of such products by the institution.

>> Advertisement – Whenever permitted by the applicable laws and rules (ANVISA resolutions, etc), the associate companies can purchase floor space and booths at Events and Congresses, seeking to advertise their products and company. This support should never be associated with the purchase of the associate company products by the institution or based on a past or future use of such products by the institution.

>> Support for Events and Congresses – Whenever permitted by the applicable laws and rules, the associate companies can provide resources for Events and Congresses organized by third parties provided that they are legitimate, independent and for educational purposes. This support should never be associated with the purchase of the associate company products by the institution or based on a past or future use of such products by the institution.

>> Fellowships – The associate companies can offer educational donations to training institutions, healthcare institutions or professional societies for the purpose of medical education programs. Such donations can be made through financial support to partners and fellowships (accepting to cover travel costs, instruction, accommodation, food, etc.) in fields associated with their products and therapies, provided that the expenditures are linked to a legitimate need by the Healthcare Professional or by the institution. Selection of the beneficiary should be done by the institution in which the Healthcare Professional works or the teaching institution where he/she will be trained. These donations should be offered to the institution, not to the individuals. This support should never be associated with the purchase of the associate company products by the institution or based on a past or future use of such products by the institution.

Payment for social activities and entertainment is not allowed.

C – Consultancy Agreements and Research

When associate companies choose to carry out consultancy agreements with Healthcare Professionals, these agreements should clearly and precisely reflect the conditions and be well documented in relation to the services rendered, with fair payment conditions compatible with market practices, and signed by the parties involved.

The associate companies can only remunerate Healthcare Professionals for scientific services

supported by a written agreement entered by the parties before the services are provided. The services and remuneration should be proportional, that is, the associate companies should obtain something tangible from the payment of fees, and the fees should have a reasonable value as practiced in the market.

Selection of Healthcare Professionals for consultancy should be based on qualification and experience, which should be adequate for the consultancy and should not be, in any way, related to the sales volume to the consultant in the past or any future sales expectations.

The associate companies should follow and comply with all applicable laws concerning marketing or obtaining the necessary approvals from Healthcare Professionals for contracts, as mentioned before.

The consultancy contracts with Healthcare Professionals seeking research should contain the research protocol and the work plan to be followed by the consultant. Whenever prior approval of the protocol or patient consent is necessary, the associate companies are responsible for the documentation.

Payment for social activities and entertainment is not allowed.

CHAPTER VIII – Advertising and Sales Promotion

Information forwarded by the associate companies should be coherent with duly published and approved technical literature and scientific papers, as well as in accordance with regulation and legal requirements.

When advertising their products, the associate companies should maintain in their possession for the information of those legitimately interested, factual, technical and scientific data that provided the basis for the statements provided regarding the product.

Associate companies should not undertake actions that distort the market, seeking, by means of their advertising the exclusion of competing companies.

The use of technical documentation or third party information by associate companies without previous authorization by the proprietary company, is prohibited, so long as the information is not in the public domain.

CHAPTER IX – Donations

The associate companies can donate money or in-kind contributions that are aligned with their social responsibility programs. As a basic principle, donations should not induce Healthcare Professionals to buy, rent, recommend or use products of the associate companies. The donations can be characterized as charity or donations for research, as follows.

Charitable Donations

The associate companies can make charity donations, creating funds for care of the indigent, patient education, public education or sponsorship of events that result destined for charity. The associates should not make charitable donations if the donation is related to the purchase or leasing of products, as well as past, present or future recommendation to use the associate's products. For example, an associate should not approve a donation request by a Healthcare Professional, in which the Professional describes past purchases of the associate's products as a reason for the associate company to make the charitable donation. All donations should be appropriately documented and it is recommended that associate companies adopt an evaluation process for Charitable Donation requests that distinguishes between commercial and charitable activities. Examples of appropriate charity and considerations regarding this are presented below:

1. Donations for medical education. The associate companies can make donations to promote genuine medical education for students, residents and sponsored students that are charitable and have an academic affiliation or, when consistent with the introduction to this section, other persons from the medical field.
2. Public Education. The associates can make donations that aims to support patient education or public education on important topics in the Healthcare field

Donations for Research

Given the recurrent and increasing importance of industry support of independent medical research, medical education and the advancements in medical treatment, it is important to encourage this relevant function insofar as this support does not create an unnecessary risk of legal liability to the associate or the Healthcare Professional. Therefore, associates should comply with the conditions for research donations to Healthcare Professionals:

1. The research should be legitimate, with well-defined stages and results contained in a written contract.
2. The proposed research should be evaluated and the subsequent research contracts should be negotiated and managed by representatives of the associate company, who do not participate in the selling of products and services to the Healthcare Professional who will receive the research

donation.

3. Conditions associating research funds with purchases of the associate's products or services by the Healthcare Professional should not exist (unless the products and services are purchased for the research itself). The research funds cannot be contingent on or linked to past, present or future sales of products or services by the associate company to the Healthcare Professional.

CHAPTER X – Thirds Parties Acting on Behalf of Associate Companies

The associate companies should ensure that all third parties who maintain contact with Healthcare Professionals and clients on their behalf to intermediate sales of products (such as independent or contracted sales representatives, distributors, sub-distributors, agents, consultants, etc) are properly trained so that they have sufficient knowledge to clearly and responsibly present information on their products, commercial practices and relationship policies with the public.

The associate companies should demand that third parties who act on their behalf maintain high standards of commercial ethics, including guidelines established in this Code of Ethics.

The associate companies should channel their best efforts to adopt adequate selection processes for third parties, as well as directly or indirectly supervise the services of contracted third parties acting on their behalf. The associates should also take immediate action to terminate contracts with third parties that do not comply with the ethical and legal principles applicable to the business, and communicate the commercial practices that violate this Code or the relevant legislation.

CHAPTER XI – Violations

The associate companies that disregard any disposition of this code and/or legal dispositions shall be reported to the Ethics Committee so that within 60 (sixty) days it shall analyze, discuss and judge the matter , in accordance with the specific Internal Regulation.

The penalties that shall apply to the companies (without excluding the necessary judicial action and notification to the competent government and review authorities) in the judgment of the Ethics Committee maybe the following:

- a) Determination that the violating company ceases the prohibited activity;

- b) A formal warning to the violating Company;
- c) Temporary suspension of the rights as an ABIMED associate;
- d) Elimination from the organization in the event of a violation of the decisions established by the Ethics Committee, or repeating the prohibited practice;
- e) Legal action against the company, based on material evidence, without prejudice of notifying the competent authorities, as determined by law.

All the points mentioned above based on Analysis of Violations Procedure of ABIMED's Ethics Committee.

CHAPTER XII – Responsibilities

It is the responsibility of the associate company to observe the rules of conduct established in this Code of Ethics, even when represented by third parties acting on its behalf.

This Code should be reviewed every two years from the date of its publication.

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HISTORY OF PREVIOUS EDITIONS OF THE ABIMED CODE OF ETHICS

- 2nd edition – November 2007.
1st edition – November 2006.

MORE INFORMATION ON THE CODE OF ETHICS:

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*** Our special thanks to Santiago Rabassa and Gabriela Roitburd (Auto Suture/Covidien) who gently reviewed the English version of this Code. ***