Interaction Code along with Health Care Professionals 2019
INTERACTION CODE ALONG WITH HEALTH CARE PROFESSIONALS

Submission 3

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SUBMISSION

The Asociación Mexicana de Industrias Innovadoras de Dispositivos Médicos (AMID) is a non-government, non-profit group of leading medical device and diagnostic systems companies, which promotes health services improvement in Mexico through access to medical health services advances enhancing improvement in people's life quality.

The AMID member companies are the main companies of medical devices and diagnostic systems in the world and are compelled to perform the ethical standards established according to the Codes.

Medical devices and diagnostic systems tend to depend heavily on Health Care Professionals active participation from the beginning to the end, compared to drugs products or biological substances that may act in the human body by pharmacological, immunological or metabolic means. Overall, medical devices and diagnostic systems work as an extension of the doctor's hands, in some circumstances, assist Health Care Professionals in the diagnosis, monitoring and treatment decisions; they create synergy along with other technologies or products under different conditions, guaranteeing a safer and more efficient use.

The scope of beneficial relationships between Health Care Professionals and companies is extensive and includes predicate interactions. Among these interactions’ aims, we can mention the following:

• Foster the medical devices and diagnostic systems breakthrough. The development and improvement of medical devices and forefront diagnostic systems are collaborative processes between companies and Health Care Professionals. Innovation and creativity are essential aspects for their development and evolution, which usually occur outside the companies’ laboratories.

• Reinforce the safe and effective use of medical devices and diagnostic systems. For security and effective use of medical devices and diagnostic systems, companies are generally required to provide appropriate technical support, service, education, training, and instructions to Health Care Professionals. Occasionally, regulatory authorities require such training as a condition for products approval.

• Impulse research and education. The support provided by companies for medical research in good faith, the education and promotion of professional skills increases the patient safety and increases access to medical devices and diagnostic systems.

• Provide open and transparent environments in which companies have a greater participation in global market.
AIM

This Code establishes standards for the ethical promotion of medical devices and diagnostic systems aim for Health Care Professionals, in order to ensure that the Associates and Professionals relationships are adequate, and they are perceived as such. The guidelines described in this document are consistent with provisions issued by International Organizations such as Eucomed, AdvaMed and APEC; and are based on the following principles:

- **Reliability:** Act with honesty, sincerity and fairness with all parties.
- **Separation:** Relationships with Health Care Professionals should not be used to influence or bias, through undue or improper advantages, their purchasing decisions, that interaction shouldn't depend on sales transactions or the use or recommendation of products from AMID associates.
- **Congruence:** Agreements with Health Care Professionals must meet the commercial standards, as they are accurate, fair and unbound for corrupt purposes.
- **Development:** Relationships with Health Care Professionals are aimed at promoting medical technology, innovation; and patients' life quality care and improvement.
- **Transparency:** Health Care Professional interaction must have a clear purpose and scope; always meeting national and local laws, regulations or professional codes of conduct.

It is each one of the associated companies' liability, through their key administration, to ensure that all their employees are aware of these obligations and that all needed measures are taken to prevent, detect and report any Business and Ethics Codes of the AMID violation.

It is a required that all AMID Associates meet the Association's Codes.

It is a known fact that Associates can interact with Health Care Professionals directly or through commercial intermediaries through which Associates act already under a distribution, integration, commercial agency, commission, or any other, under Mexican regulatory framework.

In this regard, it is expected that AMID Associate companies draw up a formal contract with their Commercial Intermediaries. This contract must boast a compulsory enclosure including the explicit acceptance by each third party of the AMID Codes and must comply with the legal obligations of the country where it enters into.

The AMID Associates are committed to perform this code and are responsible for requiring that Commercial Intermediaries that commercially represent the AMID Associates perform it too. Any AMID Codes violation by a third party is responsibility of the AMID Associate and therefore, may be subject to sanctions determined by the AMID Codes.

In the event that the Associates internal codes involve more stringent provisions or interpretations than those contained in the AMID Codes, the Associates are required to apply the strictest ones.
The AMID Associates are responsible for monitoring and verifying that violations of this Code are amended, as well as ensuring that internal structures and procedures are created (including adequate training for their employees and their Commercial Intermediaries), to ensure that activities with the Health Care Professionals are carried out in a responsible and ethical way.

AMID is open to receive complaints, regarding the source, related to any aspect of this Code, all in concurrence with the prescribed for the Complaints Procedure for AMID's Current Codes Infringement. When it is determined that a code's infringement has occurred, the aim is to correct the infringement as soon as possible.
CHAPTER 1

1.1 Definitions

i. **AMID** - Asociación Mexicana de Industrias Innovadoras de Dispositivos Médicos A.C.

ii. **Promotional items** - Objects that are given to Health Care Professionals and are used to promote the Associates’ brand.

iii. **Associates** - They are all those juridical persons that conform the AMID by the Board of Directors of the Association agreement.

iv. **Good of Value** - It is any quantifiable benefit in money or in kind, including without limitation: movable or immovable property, trips, donations, contracting services or the promise of conferring upon them.

v. **Medical Device** - It is any instrument, device, utensil, machine, implant, diagnostic agent, material, substance or similar product, including software for its operation, to be used, alone or in combination, in human beings; with any of the following intentions:

   - Diagnosis, prevention, surveillance and / or auxiliary in diseases treatment;
   - Diagnosis, monitoring, treatment, protection, absorption, drainage or auxiliary in healing a lesion;
   - Research, replacement, modification or support of anatomy or a physiological process;
   - Life support;
   - Conception control;
   - Medical devices disinfection;
   - Disinfection substances;
   - Information given through samples in vitro examination taken from the human body for diagnostic purposes;
   - Devices that incorporate tissues of animal and / or human origin;
   - Devices used for in vitro fertilization and assisted reproduction technologies;

   And which main use intention is not through pharmacological, immunological or metabolic mechanisms, however, they can be assisted by these means to achieve their function. Medical devices include health supplies for the following categories: medical equipment, prostheses, orthoses, functional aids, diagnostic agents, supplies for dental use, surgical materials, healing materials and hygiene products.

vi. **Government entities** - Agencies, instrumentalities or national, state or local public bodies, as well as government control companies.

vii. **Events** - These are the congresses, symposia, courses and their complementary educational events also called satellite symposia, scientists or professionals tending to support medical science improvement, Health Care and Patient Professional’s education; or independent medical research.

viii. **Entertainment Events** - Any assets or cultural, recreational or entertainment content event which are not limited to: Sports, tourism, theatre, golf, skiing, holiday activities, regardless the
value that the activities themselves may have, their flares and the time devoted to them.

ix. **Government Official** - Any national or foreign government employee who works for a **Government Entity**, including but not limited to: federal public servants, state and municipal public administration; legislators, judiciary representatives, national or foreign health sector employees, customs offices personnel, tax collection offices and all authorities related to health laws and regulations and other applicable laws. Any hospitals affiliated with public education or military institutions employee shall also be considered as a government official; as well as any government entity employee working in health care facilities or those involved with government entities and political parties’ members, the same officials or officials’ candidates.

x. **Modest or reasonable expenses**: This category is considered as expenses that comply with the hospitality table established in **this Code, Alienation 1**, as well as the expenses that are considered average within a geographical area and in relation to the Fair Market Value.

xi. **Commercial Intermediaries** - Are those natural or corporate bodies, of Mexican or foreign nationality, who act on behalf, for account, or for any of the Associates' interest, with Health Professionals in Public and / or private sector and that by virtue, are in a position to influence the conduct or decision of the third party in order to attract or retain business, such as: Distributors, sub-distributors, agents, sales representatives, representatives, principals, assignees, brokers, counsels, managers, consultants, subcontractors, sales representatives or employees, value-added resellers and / or channel partners,

xii. **Paradisiacal Places**: All those mentioned in this Code, Alienation II.

xiii. **Scientific educational material** - Design articles or didactic content, which purpose is to make tools available for **Healthcare Professionals** that help determine patients or the same Health Care Professionals' doubts quickly and friendly, among others, we can mention anatomical models, books or material for optical, magnetic and electronic support.

xiv. **Bribery and / or Improper Payment** - Any unlawful action consisting on: Offering, suggesting, promising or delivering money, gifts or any Good of Value to a **Health Care Professional** and / or **Government Official**, in exchange for any of them performing or refraining from performing an act related to their duties, which purpose is obtaining, or managing businesses in the institutions in which they provide their services to obtain or maintain an undue benefit or advantage over other participants. Is considered **Bribe and / or undue payment** regardless of the acceptance or receipt of the money, gift or **asset of value**, or the result obtained.

 xv. **Related Parties**: Any person who is linked to the **Associate** or a **Health Care Professional** either by filiation, sentimental relationship, labour relations, professionally or for businesses, can be the ascendants, descendants, collateral up to the fourth degree, spouses, concubines, friendships in general, partners or societies which the **Associate** or **Health Care Professional** are part of.

xvi. **Health Care Professional** - Are all those professionals, technicians and assistants practicing health care disciplines, who are able to perform within the public or private sphere and that includes but are not limited to the following: doctors (including all the specialties and sub-specialties of present and future medicine), laboratory personnel, dentists, veterinarians,
biologists, bacteriologists, nurses, social workers, chemists, psychologists, sanitary engineers, nutritionists, dietologists, pathologists; as well as any person who works in administrative areas within a health care institution, such as: buyers, comptrollers, hospital directors, warehouse personnel, and all those who are established as such by other legal provisions applicable.

xvii. **Fair Market Value** - A payment or benefit value in kind as a fair and adequate remuneration to the Health Care Professional for their rendered services, privileges furnished or performed work considering commercially legitimate factors that can be demonstrated objectively, without noticing aspects such as the sales volume or any return or purchase value.
CHAPTER 2

2.1 Relationship with Health Care Professionals

The Associates and / or AMID Commercial intermediaries are bounded to refrain from making, directly or indirectly offers, promises or payments authorizations in cash or valuable goods failing in what is determined for the federal or local laws, anti-corruption conventions Mexico is part of, the institutions codes of ethics and this Code provisions. The above, knowing that all or a part of the money mentioned, or the Good of Value has the aim of unduly influencing any Health Care Professional, and / or Government Official, client or person act or decision. Likewise, no Associate may influence any Health Care Professional, and / or Government Official, client or person.

Likewise, no Associate and / or Commercial Intermediary may influence any Health Care Professional, and / or Government Official, client or person to breach their legal obligations, or to unduly affect any authority act or decision.

The AMID Associates are committed to promote their products by encouraging the Medical Devices and diagnostic systems’ proper use by advertising them objectively; avoiding deceptive advertising or exaggeration of their properties, which could lead to error for Health Care Professionals in decision making.

Likewise, each Associate must have internal policies containing a definition of the amounts that adjust to the expenses reasonableness by mentioned items in this document; in line with local regulations and what is mentioned within this Code. Members may apply for documentation that observes their internal policies or practices as support for any of the supports conferred upon, directly with Health Care Professionals or government officials.

2.2 Meals

Meals with Health Care Professionals can be part of educational activities designed to give them a deeper knowledge for any of the associates’ products.

These should be occasional, based on the tabulation contained in Alienation I, aiming to present scientific, educational or business information. They must be carried out in appropriate places for the aimed purpose and will not be part of any entertainment or recreational activity.

Members may pay for Healthcare Professionals’ meals which whom they are exchanging information with. The cost of meals will not be covered by any other person outside the interaction.

Members may provide food for Health Care Professionals in demonstration, educational or training activities that partners conduct to provide a better understanding of their products. At working or business meetings, Associates may pay for health Care Professionals meals and those who must be present because they are professionally related to the topic and information that will be shared at that meeting.

The Associates will seek to ensure that these types of meals are modest and occasional, that they take place in appropriate places for their actual purpose (preferably in places where the educational
activities are carried out) and that they do not include or take part of any entertainment or recreational activity.

The cost of meals cannot be covered by Health Care Professionals or employees of the medical institution who are not present at the event; nor expenses for the food of other companions or related parties, or for people who do not have a professional interest in the information that will be shared at the meeting.

### 2.3 Entertainment

AMID associates are not committed to sponsor any activity or Entertainment Events. They may only participate or offer activities that are part of a program for medical purposes - scientific and / or educational exchange.

### 2.4 Gifts

AMID associates will not grant gifts under any circumstances to Health Care Professionals.

### 2.5 Educational and / or scientific material

It refers to the material defined in paragraph xvi, Chapter I, Definitions, which brings together features and resources that provide understanding, teaching, learning and is provided to Health Care Professionals exclusively for educational or scientific purpose, and should be related to medical practice. The granting of this material does not compromise the prescription, purchase or recommendation of a product. Its cost should not exceed $750 (seven hundred and fifty pesos 00/100 in national currency), excluding anatomical models. Its granting must be properly logged regarding the case, frequency and purpose by the conferring upon company.

### 2.6 Promotional items

By conferring upon Promotional Items, associates are expected to perform the following requirements:

- They should always boast the printed logo that represents the Associate's brand (s).
- They have a promotional or advertising purpose.
- The unit cost should not exceed $ 200.00 (two hundred pesos 00/100 National Currency) or USD $ 10.00 (ten US dollars) trade in value.
- Not to be conditioned, nor serve as incentives for the product's purchase or prescription.
CHAPTER 3

3.1 Sponsorships (scholarships) for Health Care Professionals

The AMID Associates, in their commitment to the best practices for health industry and in order to prevent conflicts of interest of any kind, have agreed on the following rules for conferring upon sponsorships to avoid involving concessions for special prices granting, rewards or conditions for the prescription or products purchase or Associates services:

- Funds may only be provided, in cash or in kind, to support the medical science, Health Care Professional education, and the patient or independent medical research improvement, through an organization, association, institution or formally constituted foundation for such purposes, being the only ones responsible for the sponsorship beneficiary selection.

- It will not be allowed to sponsor, directly or indirectly through a Commercial Intermediary or a Health Care Professional to attend Events performed by a third party, in order to prevent it from being used and interpreted as an inappropriate incentive.

- It is strictly forbidden to sponsor through scholarships for Events in Paradisiacal Places referred to in this Code, Alienation II, with the intention of preventing it from being used and interpreted as an inappropriate incentive.

- No funds will be provided for Entertainment Events under any circumstances.

- Commercial activities (stands) are not considered sponsorships.

- It must be ensured that there is the appropriate documentation concerning all the activities to be carried out.

3.2 Courses and Product Use Training (Own event sponsored by any of the Associates)

The training and demonstration programs carried out by the Associates must have the primary aim to promote medical knowledge and training relating the safe and effective use of any Associates' products.

These activities must be carried out by qualified personnel.

Based on the above, the associates will be able to give courses, symposia, demonstrations and training to their distributors, clients and Health Care Professionals, which may or may not occur at the Associate's facilities and may be carried out by more than one day. In this type of Events, leisure should not be encouraged, as well as recreation or entertainment. In case of Health Care Professionals attendance, events should not be carried out in Paradisiacal Places referred in this Code, Alienation II.

When training in the offices of any of the Associates or the Health Care Professional is impractical or inefficient, the Associates may cover transportation and hospitality expenses, as well as offer a reasonable feeding cost related to this training.
Likewise, the organizer must keep the above Event mentioned documentation (agenda, assistants, related expenses and post-facto evidence) and their respective authorizations.

It is forbidden for the organizer to cover any expense, including but not limited to transportation and hospitality, for Health Care Professionals companions or other guests not involved in the Event.

The training activities must be carried out without being a commercial commitment condition and should not be considered as concessions for special prices granting, rewards, or conditions for the prescription or products purchase or Associates services.

### 3.3 Marketing and Promotion Meetings

When meetings are held to discuss products, negotiations or procurement terms at different locations to the Health Care Professional's (for example, visiting manufacturing plants), the associate will be allowed to cover the transportation and lodging expenses, according to the internal policies which the Associates count for this purpose with, as well as this Code established guidelines. Related to these information exchange meetings, reasonable food expenses may be covered.

The Associates will not cover Health Care Professionals guests or other companions who may participate in the mentioned above meetings expenses and will observe the cost table referenced in this Code, Alienation I.

In case of Health Care Professionals attendance, meetings should not be at paradisiacal places referred to in this Code, Annex II.

### 3.4 Traveling and Accommodation

It is appropriate to pay for a trip and lodging costs related to Events, courses and product training, education or equipment demonstrations according to the following guidelines:

A. Travel expenses, lodging and meals generated from the day before the event and up to one day after the end of the event, may be covered, in case the itinerary requires so.

B. The stay must be at the hotel hosting the event or at hotels with a similar rate, in these spaces the Associate will not pay the additional expenses that are above the hotel's lodging rate. All participants must stay in standard rooms.

C. First class flights are not allowed. All participants will travel in economy class. When there is a proven medical impairment or trips of more than six continuous hours of flight; that requires that the participant travels in Business Class, it will be the AMID Associates power to approve and document it according to its internal policies. This should also be considered according to the internal guidelines of each company.

D. It is forbidden to pay for travel, lodging and meals for any HealthCare Professional companions and / or visitors.

E. In the case of meetings to discuss products, negotiations or terms of sale in a different location to the Health Care Professional's (for example visiting the
manufacturing plant), the associate will be allowed to cover the expenses of transportation and lodging under this section terms.

F. No excursions, recreational activities or additional expenses such as laundry, *room service* or other services will be paid.

G. The associates will follow their internal processes and use their contracted travel agencies services for these activities’ organization, avoiding as possible, the reimbursements or direct payments to **Health Care Professionals** for these concepts. Cash payments are not allowed.

H. In case of **Health Care Professionals attendance** this should not take place at paradisiacal places referred to in this Code, Alienation II.

### 3.5 Research

Associates may provide any support and / or contract Healthcare Professional services to perform medical and / or scientific research, on promoting clinical improvement for patients benefit purpose, provided that they are in accordance with laws and local regulations and meeting the following requirements:

- A. To conduct the investigation, there must be a predicate application addressed to the **Associate**, in writing.
- B. Benefit form a formal investigation protocol and obtain all the clearances that may be needed for it to be carried out.
- C. The agreement entered into, to receive any support, should consider the following aspects, among others:
  - i. The research protocol, indicating the institution and the responsible (related) researchers in charge of carrying out the studies.
  - ii. The name and aim of the study to be carried out.
  - iii. Clauses on how to perform the protocol.
  - iv. Supporting ways and resources allocation.
  - v. Ways for periodically and definitively delivering results reports.
  - vi. Communicating the results to the scientific community, as well as any adverse incident.

Researchers must boast the required skills and capacities and the institution must have adequate facilities to carry out the clinical studies in question. The compensation must be determined according to Fair Market Value and should not be related to the volume or value of past, present or future business.

Likewise, the research must have a well-defined objective and term and in no way, should be linked to Associate's products or services of the past, present or potential commercialization.
CHAPTER 4

4.1 Service Contracts with Health Care Professionals

Associates can hire consulting services and / or advice from Health Care Professionals, such as: presentations in training sponsored by any of them, the workshops, conferences and product demonstration delivery, through which the partners compensate the Health Care Professional at a fair value.

There must be a previously identified and legitimate requirement of the services contracted, and they must not have the purpose of inducing the service providers to buy the associates products. The work done by Health Care Professionals should be developed in an appropriate place according to the services provided type.

The selection of Health Care Professionals for providing services must be exclusively based on their experience and qualifications to cover the need.

The Health Care Professionals number to be considered to provide services, should be fully justified due to aspects such as the event program, the participants, sessions, among others.

The compensation must be determined according to the Fair Market Value and not in relation to the volume or value of the past, present or future business along with the Health Care Professionals mentioned before.

The contracted services must be documented in writing with an adequate description of the service provided; their consideration must be required, cleared and formal, prior to the service completion. Payment must carry the name of the person who has provided the services, applying local taxes and must be related to legal requirements. There should not be payments by cash.

If the Health Care Professional provides services for a Public Institution, he / she will be responsible for having the corresponding authorization as applicable according to current regulations, prior to acceptance.

Associates may pay or reimburse the costs for food, transportation and lodging incurred by Professional Health Care in connection to provide services based on the provided in this Code, Chapter 3, paragraph 3.4 Traveling and Lodging. This must be documented and formally cleared.
CHAPTER 5

5.1 Donations to Charitable Institutions

Donations are part of the partners’ community commitment and reflect our identity as responsible corporate citizens. All donations must be according to the following:

a. There must be an appropriate evaluation that supports it is not granted to influence unduly, or for inappropriate activities. Likewise, it can obey an express request or a proactive offer.

b. Donations must be carried out to Private Assistance Institutions or other non-profit organizations authorized for this purpose, according to the Current Law. Under no circumstances donations should be carried out to individuals or on behalf of a Health Care Professional.

c. The donation must not represent the obtaining of commercial advantages nor to condition the past, present or future procurement.

It will be the Associates liability to implement procedures to guarantee compliance with the above.

CHAPTER 6

6.1 Samples

Each Associate must benefit from internal policies that protect the issuing and proper use of the samples.

Provided that local laws and regulations allow it, a free product sample can be provided to a Healthcare Professional for demonstration evaluation, familiarization and / or education of the products of the associates purpose, in order to improve the attention to the patients. Said samples cannot be sold or used inappropriately, i.e. outside of the objectives previously indicated. All samples:

a. Must contain a label that identifies them as such, differentiating them from the authorized products for sale.

b. They must be provided in quantities and frequencies that allow an adequate evaluation according to what each Associate determines based on the medical criteria applied to the device in question.

c. They must not be conditions for a sell up execution or to be understood as a service compensation.

d. The samples issuing must be adequately documented prior to, and after delivery.

6.2 Products or demonstration equipment

The equipment or products that are conferred upon for demonstration may be granted for a period determined by each Associate and by virtue of their internal criteria and policies, with a maximum term of one year, in order to allow the Health Care Professional to perform an appropriate evaluation.
Such events should be adequately documented prior and after to minimize the risk of an improper financial benefit being provided to a Health Care Professional. The companies must ensure that the products or equipment in demonstration are returned or properly discarded, as determined by their nature, at the end of the evaluation period, if they were not acquired.

Members may request for additional documents needed that allow them to recover the equipment or products as dictated by their internal policies.

CHAPTER 7 Associate Commercial Intermediaries liabilities in interaction with Health Care Professionals.

The AMID Associates recognize that in their commercial performance and interaction with Healthcare Professionals, they are represented by the Associate’s Commercial Intermediaries and is vitally important that these Intermediaries know this code’s provisions in order to ensure its compliance.

All the provisions contained in this code will be applicable to Associate’s Commercial Intermediaries; meaning, the Associates are bounded to communicate the provisions of this code and train their employees and Commercial Intermediaries and shall establish the necessary mechanisms to ensure that their Intermediaries adopt these provisions as part of their internal regulations and accordingly, they must observe a congruent behaviour.

8 Legal Framework

This Code purpose is to establish a self-regulation way for the interaction between the AMID Associates, the Intermediaries through which they act, and the Health Care Professionals. The previous, to generate relationships based on ethics and transparency in business, as well as the promotion of the Associates compliance along with national and / or foreign regulations whose compliance is observable to them, such as the standards that make up the Sistema Nacional Anticorrupción Mexicano, Ley de Prácticas Corruptas en el Extranjero (FCPA foreign Corrupt Practices Act, and the UK Bribery Act).

8.1 Validity and Code Modifications (revised version by April 15)

This version of the Code will entry in force on July 23th, 2019 and will be subject to review every two years.

This Code may not be modified or altered in whole or in part, unless said modifications are in writing and accepted by the AMID’s members, according to bylaws. The Associates will sign a communicative document every year during the first quarter of each calendar year, signing their commitment to observe the code. The lack of a signature of the prior communication will empower the AMID not to renew the associate's affiliation.

Likewise, Commercial Intermediaries must be required for the compliance of this Code.
Alienations

Alienation I. Meals in national territory.

<table>
<thead>
<tr>
<th></th>
<th>Breakfast</th>
<th>$ 450.00 (four hundred and fifty pesos 00/100 MN) / USD $ 23.00 (twenty-three US dollars)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Food or dinner</td>
<td>$ 1,350.00 (one thousand three hundred and fifty pesos 00/100 MN) / USD $ 68.00 (sixty-eight US dollars)</td>
</tr>
</tbody>
</table>

* Does not include tips and taxes
* Price per person
* It is not allowed to accumulate the amounts not used per day to make a single payment for food
* This is a guide for associates which can be updated annually or as appropriate, as a variation in the exchange rate of the dollar versus the Mexican peso and inflation costs.

Alienation II. Paradisiac places in national territory.

1. Riviera Maya
2. Cancun
3. Acapulco
4. Cozumel
5. Los Cabos
6. Riviera Nayarit
7. Puerto Vallarta