



GLOBAL COMPLIANCE MANUAL
QUALITY-1 HOLDINGS & AFFILIATES

November 2016

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Introduction

The Global Compliance Manual (this manual, hereinafter referred to as the “**Manual**”) establishes the expectations and requirements of Quality-1 Holdings and Affiliates¹ (hereinafter referred to collectively as “Quality-1 Holdings”) for all persons, employees, collaborators, affiliates and other external entities (collectively, the “Suppliers”) to which we require to act according to the Applicable Laws and Regulations, as defined further on in this Manual. In its broadest sense, Suppliers are all those external parties that occasionally may represent or provide services to Quality-1 Holdings, or that may participate in any way in selling their products, i.e. affiliates, independent subcontractors, distributors, businesses, brokers, employees, close relatives (such as defined hereinafter in this Manual), as well as customs agents or regulatory agencies professionals and other third parties that interact with the Quality-1 Holdings management.

Quality-1 Holdings has prepared this Manual in order to guarantee that our Suppliers abide by the same ethical standards established for Quality-1 Holdings and by the legislation of the countries where we operate. As a condition for maintaining a commercial relationship with Quality-1 Holdings, each Supplier should comply with the provisions of this Manual, the Reference Guide, the Code of Ethics and any other Compliance policy that Quality-1 Holdings may communicate occasionally. Should any of the Compliance requirements of the present Manual come into conflict with the provisions of a written contract entered into between the Supplier and Quality-1 Holdings, the terms of this Manual shall prevail. **In case the legislation, codes of conduct or any other applicable regulations in a specific country or region are more restrictive or require the approval of a transaction by the pertinent public authorities, the more restrictive requirements should be complied in full.** Any doubt or observation related to this Manual should be addressed to the Quality-1 Holdings Compliance Department (hereinafter referred to indistinctly as “Compliance Department”). Contact details are related at the end of this Manual.

Si la legislación de las actividades empresariales del Proveedor es más estricta que las disposiciones de este Manual, deben seguirse las normas aplicables más estrictas.

Section 1. General Principles

General background and certification

We require that, in exercising their activities, the Supplier and their owners, directors, dignitaries, employees, sub-distributors, agents or representatives (hereinafter referred to collectively as “Representatives”) strictly comply with all policies, codes, procedures, laws, regulations, bylaws and requirements of the applicable public administrations. The Supplier shall be responsible for obtaining all the necessary permits or licenses required by the public authorities for exercising activities related to Quality-1 Holdings. In any formalities before the public organizations and other entities, the Supplier shall abide by the highest standards of honesty, integrity, good faith, fair deal and ethical conduct. The Supplier subscribes to the following:

- **Anticorruption statement.** Neither the Supplier nor any of their Representatives has been or is being:
 - (i) Investigated, fined or sentenced for infringing the US Foreign Corrupt Practices Act, “FCPA”, the national anticorruption/antifraud legislation or any other anticorruption/antifraud law that may rule the activities of the Supplier concerning their commercial relationship with Quality-1 Holdings;
 - (ii) Investigated, fined or sentenced for infringing any regulation concerning medical devices, or
 - (iii) Separated, excluded, suspended or declared unfit in any other way for participating in any medical care program of the public administrations.

- **Statement about complaints of the competent authorities.** Neither the Supplier nor any of their Representatives has been subject to a claim by the competent authorities due to alleged criminal actions, felonies related to the practice of medicine or any other illicit action concerning fraud or theft.

In case any of the previous events occurs during the validity of the commercial relationship with Quality-1 Holdings, the Supplier shall notify Quality-1 Holdings immediately in writing the existence of such actions, inquiries or legal procedures.

- **Compliance with the policies, procedures, standards and requirements of the company.**

During their commercial relationship with Quality-1 Holdings, both the Supplier and their Representatives should comply with all applicable laws and regulations, all Quality-1 Holdings policies, procedures and programs and all the training requirements, including, without limitation, the following:

- The FCPA;
- This Manual;
- Reference Guide for Central America
- Applicable code of conduct or ethics, if any, of the medical devices sector from the Supplier's country or any other applicable sector code.
- All applicable import and export control laws
- Quality-1 Holdings Compliance Training Programs, and
- All other Quality-1 Holdings policies, procedures and programs that are effective or that may be approved anytime and notified by Quality-1 Holdings to the supplier.

(Collectively, the "Applicable Laws and Regulations")

The Supplier shall take the necessary steps for guaranteeing that all their Representatives comply with all the applicable laws and regulations. The Supplier is obliged to provide copies of the Applicable Laws and Regulations to their Representatives involved in commercial relationships with Quality-1 Holdings, which in turn, are obligated and should be obligated to comply.

The Supplier shall cooperate with the Quality-1 Holdings Compliance Department and, for such purpose, shall reply to all information requests, implement control policies and issue the certifications that such Department may occasionally require. Anytime and to its entire discretion, Quality-1 Holdings reserves the right to amend, modify or change in any other way this Manual and the remaining codes or similar policies of Quality-1 Holdings.

Training

The Supplier shall provide (directly, indirectly or through Quality-1 Holdings) any type of training and courses that Quality-1 Holdings or the applicable legislation may require, with special attention to Compliance training, to their Representatives involved in commercial relationships with Quality-1 Holdings. In case of teaching courses or training at the request of Quality-1 Holdings, the Supplier is committed to issue a certification in writing for Quality-1 Holdings with the description of the course or training taught. The courses or the training may satisfy certain requirements of their contract with Quality-1 Holdings; that is why it is important for the Supplier to provide the course or training certificate to the corresponding contact person from the Quality-1 Holdings Compliance Department. Furthermore, during their relationship with Quality-1 Holdings, the Supplier is committed to provide Compliance training and courses to any new or additional Representative as they join.

General unallowed activities

Unless this Manual specifically allows it, Quality-1 Holdings does not allow to pay or give something of value of any kind to medical care professionals (for example, surgeons) or any other public servants² with respect to the development, recommendation, manufacturing, purchase, import, export, sale or implementation of Quality-1 Holdings products. This includes, without limitations, and as an example, cash payments, commissions, professional fees (medical), discounts, bonuses, gifts, gift cards, training passes or similar in cash, and/or special favors.

Conflicts

While the commercial relationship between the Supplier and Quality-1 Holdings is valid, neither the Supplier nor their Representatives will be consciously involved, directly or indirectly, in any activity that may create substantial conflict with the loyal performance of the services, duties, covenants, commitments and obligations that the Supplier may have assumed and should carry out in order to comply with this Manual and/or the Supplier's contract with Quality-1 Holdings.

Notifications

The Supplier and their Representatives should notify Quality-1 Holdings immediately about the existence of any legal action, proceedings or investigation regarding the products or the operations of Quality-1 Holdings or the modification of any of the foregoing statements if they cease to be true.

Furthermore, Quality-1 Holdings requires the Supplier to notify them in writing immediately about the existence of any violation or suspected violation of any of the Applicable Laws and Regulations, as well as the policies or procedures of the Supplier related to legal matters or regulatory compliance. The notification may be carried out through the corresponding Compliance contact person from the list at the end of this Manual.

To the extent that the applicable legislation allows it, the Supplier's reports will be treated with confidentiality and will be used exclusively for addressing the specific problem at hand. To facilitate communication, Quality-1 Holdings has an assistance line on ethics for

² **Public Servant: the term public servant must be interpreted in broad sense.** It comprises (1) public administration officers and employees, (2) officers and employees of international non-governmental organizations (for example, the World Health Organization, Doctors Without Borders, the Red Cross), and (3) any person responsible for assigning or influencing on the assignment of public funds, including persons providing their services in consultancy, honorary or unpaid positions and private doctors whose patients benefit from public insurance programs. **The term public servant also includes any medical care professional that works for, acts on behalf of or is affiliated with medical offices, sanitary institutions, universities and public hospitals.**

submitting a report by email to the following address: cumplimiento@quality-1.com, or by phone.

If a **telephone call** is preferred, the corresponding post office box address should be enough to locate the phone number of the country and follow the indications. The call will be answered in Spanish. If another language is required for the call, the desired language should be indicated for requesting an interpreter. Locating an interpreter may take between 1 and 3 minutes. You have to wait in line during such time and not hang up.

Section 2. Provisions specifically related to Distributors

Distributors owned by Healthcare Professionals

In order to avoid any conflict of interest or violation of the Applicable Laws and Regulations, the Supplier and their Representatives should refrain from:

- Promoting or selling Quality-1 Holdings products to themselves as medical professionals, their employees or the medical institutions that may have an interest of ownership, or for the use of a surgeon, of another medical care professional or an employee or agent of an education or medical care organization owned by a close relative of the Supplier, their owners, employees, representatives, subdistributors or agents, or
- Receiving any kind of payment, commission, benefit and other advantages concerning such sales.

In this Manual, a “**close relative**” of the Supplier and of any of their Representatives, will be the spouse, parents, biological or adoptive children or siblings, stepmothers and stepfathers, stepchildren, step brothers and sisters, parents-in-law, sons-in-law, daughters-in-law, brothers-in-law, sisters-in-law, grandparents or grandchildren, or the spouse of a grandparent or grandchild, or any person that in any way has a close relationship that may imply preferential treatment.

Elusion of conflict of interest created by family ties

The Supplier will avoid at all times making an impression of using their family ties to improperly influence decision-making concerning purchases made by medical care professionals or sanitary organizations. Therefore, Quality-1 Holdings recommends to stay away from the participation or contracting of sales representatives that are close relatives of, or that have other family ties with a medical care professional, or with any other employee, agent or representative of any education or health organization. Should the Supplier hire or contract the services of any person with such type of relationship, the Supplier should comply with the following established provisions. The Supplier should also take into account, among other factors, (i) whether the sales representative has the required qualifications for the job, (ii) whether the sales representative is the most qualified candidate for the job, (iii) whether the retributions of the sales representative are in keeping with its obligations, and (iv) whether the medical care professional or employee of the sanitary organization has recommended the sales representative. Likewise, the Supplier should not allow the sales representative to promote or sell Quality-1 Holdings products to any close relative of the group of practice.

The sales representative should refrain from: (i) promoting or selling Quality-1 Holdings products to, or for the use of, an orthopedic surgeon, another medical care professional or an employee or agent of an education or sanitary organization that is a close relative of the Supplier or sales representative, in case such relative is in a position of influencing, giving an opinion or making decisions regarding Quality-1 Holdings products; or (ii) receiving any remuneration with regard to such sales.³

Extension of the relationship to other parties/subdistributors/subagents.

The Supplier will not hire any subagent for the distribution or commercialization of the Quality-1 Holdings products without the previous written approval of Quality-1 Holdings, which will grant it to its entire discretion. Any natural person or legal entity may only have the option of becoming a sub-distributor or agent of the Supplier provided (1) it is an employee of the Supplier or is obligated by a similar contract to guarantee the compliance of the contractors with the Compliance policy of Quality-1 Holdings and the Supplier, and (2) if Quality-1 Holdings has approved the implication of such natural person or legal entity, which should have complied with all the requirements that Quality-1 Holdings may establish anytime for the sub-distributors. In hiring a sub-distributor/subagent, the Supplier should make sure that such party does not violate any provisions stated in the contract between the Supplier and Quality-1 Holdings. The representative of the Supplier and the Supplier's own company will be individually responsible for any obligation executed by a sub-distributor/subagent with regard to their contract with Quality-1 Holdings.

Distributors and Tenders

Any expenses that Quality-1 Holdings attempts to collect or should pay concerning a tender, outside of the reasonable bidding expenses (including translation fees, mail delivery, etc.) should be reviewed by Quality-1 Holdings before submitting their bid. Quality-1 Holdings will only pay or refund expenses from traveling or travel expenses of third parties (for example, travel expenses of inspectors visiting our facilities) **provided these have been approved in advance by Quality-1 Holdings and are legitimate according to the applicable legislation.** This includes the reimbursement of expenses incurred by a Distributor, consultant or any other third party implicated in a product tender of Quality-1 Holdings. Additionally, the Quality-1 Holdings Compliance Department will review any bid offer with value added (except for commitments such as providing training about the effective and safe use or any other training of Quality-1 Holdings products) before submitting the bid. The Supplier should ask their Quality-1 Holdings representative to fill out and submit the form for the previous tender approval of Quality-1 Holdings, in case such bid includes expenses other than the reasonable bidding expenses and associated costs, travel expenses, or if it includes value added proposals with a minimum term of ten (10) days prior to the tender expiration date, so that the Quality-1 Holdings Compliance Department approves such expenses or value-added proposals. For any consultation and for obtaining a copy of the

form of the Quality-1 Holdings previous tender approval, you should contact the Quality-1 Holdings Compliance Department.

Discount, bonus and credit requests

Distributors should consult their legal advisors and adopt their own written discount, bonus and credit policy in order to eliminate noncompliance risks. Quality-1 Holdings recommends considering the following guidelines when writing the Distributor's own internal policy to make sure they comply with the Quality-1 Holdings policy. The following Quality-1 Holdings policies should also be taken into account when evaluating the risks concerning discounts, bonuses and credits before making the decision of granting such requests, always keeping in mind that Quality-1 Holdings does not pretend to influence on the real price to be applied in reselling Quality-1 Holdings products: verify that there is a legitimate, commercially reasonable and transparent reason for granting a discount, bonus or credit to a client; keep in a written document a memory of the specific discount, bonus or credit provisions and the means for obtaining such price reductions (such as a specific volume discount reflected in the invoice price; as a volume bonus for the client based on purchases made within a specific timeframe, or as a volume credit for future purchases); ask the client to be obligated to comply all the applicable legal requirements concerning such reductions in price; and verify that any reduction in price will be accurately reflected on books and records.

Section 3. Specific compliance requirements for acting with healthcare professionals⁴.

Meals/Courtesies

Occasionally, the Supplier may be in a situation where a courtesy with a healthcare professional is at hand (for instance, a meal or a business dinner). Suppliers must ask their legal advisors about the specific applicable legal provisions, and if the interaction with the healthcare professional is customary, they should adopt their own meal and courtesy policy for eliminating noncompliance risks. In any situation involving a healthcare professional who is a public servant, the Supplier should consult previously with the Quality-1 Holdings Compliance Department and legal consultants. It is recommended to consider the following guidelines when writing the Supplier's own internal policy in order to make sure that the Quality-1 Holdings policy is complied with. If the legislation, codes of conduct and other applicable regulations in a specific country or region are more restrictive with regard to this matter, or if they require the approval of the public authorities or notice of such interaction to such authorities, then, as previously mentioned, the most restrictive requirements should be complied in full.

Pursuant to the Quality-1 Holdings Reference Guide, courtesy gestures should only consist of meals, receptions or similar events within a business context. Entertainment or similar activities are not permitted. Any meals, receptions or similar events within a contemplated business context, including those arising from a trip sponsored by Quality-1 Holdings, should comply with the following criteria:

- Be permitted according to the applicable laws and codes of conduct of an industrial nature or of professional associations;
- Be directly related to the business activities of Quality-1 Holdings;
- Be measured, reasonable and infrequent;
- Be subordinated to time and focused on the business purpose;
- Be held at a location apt for business activities;
- The Supplier's representative must be present during the meal;
- No cash or cash equivalents should be given (for example, gift cards or gift certificates);

⁴ A healthcare professional is a natural person or legal entity in a position that allows them to buy, rent, recommend, use, prescribe, organize or influence on the purchase or rental of medical technological products of the brands we represent, including, without limitation, medicine graduates, medical residents and interns, non-medical healthcare professionals, medicine students and/or facilities, sanitary or education entities or institutional organizations including academic medical centers, dentists, in addition to agents and employees of each of the foregoing natural persons or legal entities. It is considered that healthcare professionals are affiliated to an entity if they are employees of such entity, are enjoying staff privileges or are otherwise in a situation where they can influence on the entity.

- Each meal guest should have a legitimate commercial need. The Supplier cannot pay or reimburse meals of spouses, friends, non-essential administrative personnel of the healthcare professional or relatives of an acceptable recipient;
- No courtesy gestures should not be offered under the implicit or explicit agreement of expecting that the person may acquire, use, order or recommend Quality-1 Holdings products, nor should the courtesy gesture represent a reward for past uses, orders or recommendations of Quality-1 Holdings products;
- It would be convenient to consult with the Quality-1 Holdings Compliance Department about the adequacy of the expenses in case of any doubt as to whether the foreseen expenses will comply with the Quality-1 Holdings policies;
- Furthermore, the Quality-1 Holdings Compliance Department establishes and notifies every year the specific country directives about the adequate limits for meal expenses for healthcare professionals. The Suppliers are strongly advised to comply with such limits.

Gifts

It is convenient for Suppliers to consult with their legal advisors and create their own gift-giving policy in order to eliminate noncompliance risks. When creating their own policy, they should consider the following Quality-1 Holdings policies, given that gifts create a substantial risk according to the Applicable Laws and Regulations, or, otherwise, they should adopt the corresponding Quality-1 Holdings policy, taking into account the following:

- Should the legislation, codes of conduct or other applicable regulations of a country or region be more restrictive with this regard, or require the approval of the public authorities or communication of the transaction to said authorities, the most restrictive requirements should be complied in full;
- Except for approved educational articles⁵, promotional items or gifts for “significant life events” or “cultural tradition gifts” described below, no gifts should be given to healthcare professionals. This prohibition includes valuable objects such as golf bags, vacations and tickets to sports events, as well as more modest brand name items such as eyeglasses, surgical scrubs, pens, laptops, mugs and surgical caps. No gifts should be given to the administrative staff of the healthcare professionals, even if such persons are not healthcare professionals;
- Giving an approved educational article or promotional item occasionally to a healthcare professional is allowed if certain requirements are met. All contemplated educational articles, including some brand name promotional objects, should meet the following criteria in full:
 - Be allowed according to the laws and codes of conduct of an industrial nature or of applicable professional associations;

⁵ An educational article is any object of value that promotes the education and ongoing knowledge of medical care professionals and/or benefits the patients and complies with the Quality-1 Holding requirements through the brands they represent.

- Be infrequent and of an educational nature, or for the benefit of the patients of the healthcare professional;
- The accumulated total for educational articles during one (1) calendar year should not exceed the amount established by the Compliance Department, which should be contacted for verifying the current amount;
- No single educational article may exceed the local limit established by the Compliance Department, except for anatomical models or textbooks that may be exempt from such limit based on the local industrial code;
- Exploitation or capital expenses should not be considered for the recipient (for example, office equipment or employee retribution);
- No cash or cash equivalents should be given (for example, gift cards or gift certificates);
- All educational articles will be given unconditionally. Educational articles should not be given under the implicit or explicit assumption that the person is going to acquire, use, order or recommend Quality-1 Holdings products, or that the educational article represents a reward for past uses, orders or recommendations of Quality-1 Holdings products;
- No educational items will be given to spouses, friends or relatives of an acceptable recipient, or to other parties on their behalf or for their benefit, unless such parties can, in their own right, receive an educational article according to these standards. Under no circumstances should gifts of any kind be given to spouses, friends or relatives of a healthcare professionals on behalf of or for the benefit of such professional; and
- Educational articles should not be based on cash, cash advances or personal non-reimbursable funds.

Other gifts:

- Any gift for the “significant life events” or “cultural tradition objects” should appear on the list of approved gifts according to Quality-1 Holdings compliance. Suppliers may obtain a copy of such list through their Quality-1 Holdings or Quality-1 Holdings Compliance Department representative.
- It is convenient to consult the Quality-1 Holdings Compliance Department about the appropriateness of the gifts in case of any doubts concerning whether the foreseen expenses comply with the Quality-1 Holdings policies.

Consulting Contracts

- **Distributor Consulting Agreements.** Commonly, the Supplier should not be linked by means of service or consulting services with healthcare professionals for providing product development, evaluation and investigation services related to Quality-1 Holdings products. Should Suppliers require employing healthcare professionals for providing training and education services regarding the Quality-1 Holdings products, they should submit such request to Quality-1 Holdings. Quality-1 Holdings will work with

the Supplier in order to fulfill such needs and provide the corresponding directives for such training and education contracts exclusively. There is a list of directives that can be requested to the Compliance Department.

- **Communications with healthcare professionals about Quality-1 Holdings consulting matters.** In case a healthcare professional contacts the Supplier concerning a direct consulting agreement Quality-1 Holdings, the Supplier should inform such professional immediately that: (a) the Supplier is not authorized or allowed to deal with such matters with the professional, and that (b) the professional should contact Quality-1 Holdings directly and refrain from involving the Supplier in this type of communications. Failure to comply with such directives may result in Quality-1 Holdings being prohibited to work with said healthcare professional.
- **Identification of potential healthcare professionals for establishing a consulting relationship with Quality-1 Holdings.** Occasionally, Quality-1 Holdings may ask the Supplier, given the Supplier's knowledge of the healthcare professionals in the Supplier's territory, to identify a healthcare professional with specific experience for the purpose of establishing a possible consulting agreement directly with Quality-1 Holdings. Under no circumstances should the Supplier consider a sale or a possible sale by the identification of a healthcare professional with qualifications and experience. The Supplier will abstain from contacting or making any kind of commitment with a healthcare professional due to the request of Quality-1 Holdings; all contacts related to consulting agreements should stem from Quality-1 Holdings.

Meetings

- **Quality-1 Holdings Meetings.** The Supplier should pay or reimburse the expenses and consulting time of the healthcare professional in case of (i) meetings and events related to Quality-1 Holdings, and/or (ii) if the consulting contract of such healthcare professional contemplates such payment or reimbursement. In order to organize it, the Supplier should contact Quality-1 Holdings.
- **Third party Meetings.** Quality-1 Holdings only pays or reimburses expenses of healthcare professionals, distributors and other third parties for the attendance of the first ones to events or meetings organized by third parties if (i) the Applicable Laws and Regulations allow for such reimbursements, and if (ii) certain meeting directives for healthcare professionals established in this Manual are taken into account when deciding whether the third party meeting complies with the Quality-1 Holdings policies. The Supplier should contact the Quality-1 Holdings Compliance Department in order to get the previous approval for obtaining the reimbursement.

- **Participation in meetings.** The following are general Quality-1 Holdings directives for the attendance of healthcare professionals to third party meetings. The following definitions should be particularly observed:

- Active participation: this is when a healthcare professional makes a presentation in a meeting.
- Passive participation: it occurs when a healthcare professional attends a third party meeting as a member of the audience or a group of students.

- **General Quality-1 Holdings directives for third party meetings:**

- Healthcare professionals should be qualified for attending the meeting.
- In general, Quality-1 Holdings will not deal with requests submitted by the healthcare professionals themselves. The third party meeting form should indicate if support is being granted as a response to the request from a healthcare professional and if the Compliance Manager or delegate of UEN should approve such request.
- No support will be provided in case it is explicitly or implicitly agreed that a person is going to acquire, use, order or recommend Quality-1 Holdings products, or if such support represents a reward for past uses, orders or recommendations of Quality-1 Holdings products.
- The number of healthcare professionals being sponsored will be reasonable.
- The refund will be made exclusively based on receipts and will be limited to reasonable expenses pursuant to the rules of Quality-1 Holdings and meeting associates. No additional expenses will be refunded, such as hotel charges for additional nights, spouses or guests.

- **Quality-1 Holdings Directives for Meeting Places**

- Object of the meeting. Meetings should be mainly held for the scope of occasional activities of Quality-1 Holdings, including the promotion of healthcare education, training about efficient and safe use, scientific knowledge, medical advances or an efficient healthcare service.
- Meeting places. When addressing the meeting place, the following criteria should be considered (and the adequacy of the meeting place should be documented according to the document-keeping directives of Quality-1 Holdings):

Country and city:

- A considerable number of participants should be located in the country, region or city.

- The place will be comfortable for the participants.
- General travel expenses related to the chosen location should be reasonable.
- The place should be safe for the attendants to the meeting.
- Visa regulations of the host country should be reasonable.

Hotel/Conference Facilities:

- Hotel rates and meeting fees should be reasonable (fees can be consulted contacting the Quality-1 Holdings Compliance Department).
- The location of the hotel should not be the main attraction (*that is*, vacation resorts or other luxury places) for participants in the meeting or conference.
- Conference facilities should provide an educational environment with adequate meeting space and the necessary communication technology.

Main airport. The country should have a main airport that complies with the following criteria:

- Presence of the main airlines.
- Land transportation available at the airport.

Training scholarships and philanthropic donations

All applications for the Quality-1 Holdings training scholarships or philanthropic donations must be directly sent by the applicants (not the Supplier) to the Quality-1 Holdings Compliance Department to patrocinios@quality-1.com. The Quality-1 Holdings Compliance Department will work directly with the applicant concerning the scholarship or donation application. Quality-1 Holdings will not reimburse the Supplier any training scholarships or philanthropic donations that have not been previously approved by Quality-1 Holdings through the Compliance procedures. It is convenient that Suppliers consult their legal advisers and adopt their own training scholarships and philanthropic donations policy in order to eliminate compliance risks.

Section 4. Commerce Compliance

Import/export laws and regulations

The Supplier is required to verify that all the necessary documentation for importing Quality-1 Holdings products according to their contract is at hand. In addition, the US export legislation, including the specific regulations of the Bureau of Industry and Security, “**BIS**”, of the USA Department of Commerce and the Office of Foreign Assets Control, “**OFAC**” of the

United States Treasury Department is applicable to sales and transfers of goods, software and technology of US origin to specific final users and unlicensed destinations. As distributor of Quality-1 Holdings products, the Supplier is obligated to verify that such Quality-1 Holdings products are not diverted, re-exported or provided in any other way to other destinations or parties that:

- Are not allowed in the distribution contract;
- Appears as reference in the OFAC sanction program, described in:
<http://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx>;
- Are included in any of the lists of mandatory verification available in:
<http://www.bis.doc.gov/index.php/policy-guidance/lists-of-parties-of-concern>;
- Are subject to the United States anti-boycott laws described in:
<http://www.bis.doc.gov/index.php/enforcement/oac;v>
- May violate the sanction regulations of the European Union established in:
http://eeas.europa.eu/cfsp/sanctions/index_en.htm.

Section 5. Claim and Return Procedure

Purpose

The purpose of the claim and return procedure is to establish an effective and timely method for managing, informing and addressing product complaints to Quality-1 Holdings for their investigation. **“Claim”** is defined as any written, electronic or verbal communication pleading deficiencies related to the identity, quality, duration, reliability, security, efficacy or performance of a device once it has been released for its distribution. Claim is considered to be any indication that a device has not managed to meet the quality expectations or the performance specifications of a user or client. A claim can also be noncompliance with any of the specifications of a device, its label or packaging.

In addition to processing and analyzing complaints, Quality-1 Holdings is bound to inform the corresponding public administration regulatory authorities if it becomes aware of any information reasonably suggesting that a device commercialized by Quality-1 Holdings has caused or may have caused or contributed to a death or serious injury, or that has performed improperly and that there is a possibility that the device cause or may cause a death or serious injury if the performance failure occurs again (**“event as object of report”**). For clarification purposes, Quality-1 Holdings considers that a label error in a product is an event as object of report.

Compliance Procedures/Field Actions

The Supplier **should** comply with all Quality-1 Holdings field action notifications such as returns, corrections, product recalls and corrective safety field actions pursuant to the instructions provided in the notification. NOTE: in case that Quality-1 Holdings initiates a field action, the Supplier will receive a written notice, subject, as pertinent, to the following conditions:

1. Response should be **prompt**;
2. If the affected product has been sold, it should be notified immediately to the hospital staff of the action;
3. Hospitals and/or surgeons may be contacted in case of a field action. The Supplier can also be contacted in order to provide assistance in recovering the product at hand;
4. If a product cannot be located, the documentation proving the efforts made for its recovery should be sent to the person in charge of logistics or inventory, or to the corresponding Quality-1 Holdings Claims Department.
5. The Supplier is expected to instruct their Representatives about all the foregoing requirements.

It is important not to promise clients that Quality-1 Holdings will carry out specific tasks or to provide them with certain types of reports before Quality-1 Holdings proceeds to their legal review.

Quality-1 Holdings Professional Medical Report and Return Conditions

1. If the substitution of a failed implant is requested, a claim report form should be filled. If a repair solution is requested, a repair refund form should be filled and completed online before printing it. It is convenient to remember making a copy of the form for keeping it in individual files.
2. Products should be cleaned and sterilized before sending them. Non-sterilized devices may be considered a biological hazard pursuant to postal regulations.
3. The sterilized products and the original forms should be sent to the Compliance Department using padded packaging to guarantee product delivery.

COMPLIANCE CERTIFICATE

The Supplier acknowledges receipt of this global Compliance Manual and hereby certifies and accepts having received it, read it and be bound, as well as their Representatives, by the provisions of the Global Compliance Manual of Quality-1 Holdings & Affiliates.

Signature: _____

Date (dd/mm/yyyy): _____

Name (Uppercase): _____

Position: _____

Name of Supplier: _____

Return this form to the Quality-1 Holdings Regional Compliance Management to the following contact address:

<p>Quality-1 Holdings 6382 NW 97 Ave Doral, Fl 33178 Email address: cumplimiento@quality-1.com USA Phone: +1 (305) 593-0860</p>
