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**CONVATEC GLOBAL THIRD PARTY  
COMPLIANCE MANUAL**

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Effective November 11, 2015

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## INTRODUCTION

### ➤ Statement of Purpose

ConvaTec has always taken pride in its ability to provide superior products and superior product-related services that make a difference in people's lives. We have built a reputation of being a highly ethical company based upon three guiding principles:

We must never violate applicable laws or regulations.



We must never put our employees, customers or patients at risk.



We must never do anything that may damage ConvaTec's reputation.



Third Parties such as suppliers, distributors, brokers, consultants, agents, and vendors are an integral part of ConvaTec's business and we rely on you to help build and maintain this reputation as you carry out ConvaTec's business.

This Global Third Party Compliance Manual (the "Manual") sets forth ConvaTec's expectations of persons or third-party entities whom ConvaTec has engaged to act on behalf of the Company or that otherwise sell or promote ConvaTec products ("Third Parties"). This includes, but is not limited to, agents, distributors, vendors, and consultants. Please note that, while we ask you to review this Manual in its entirety, not all sections may be directly applicable to you in light of the work you perform for ConvaTec. For example, if you are a customs broker responsible for clearing imports of ConvaTec products, sections dealing with interactions with healthcare providers ("HCPs"<sup>1</sup>) may not be directly applicable to you.

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<sup>1</sup> "HCPs" include any individual or entity involved in the provision of healthcare services and/or items to patients, and/or are in a position to purchase, lease, recommend, use, arrange for, or influence the purchase or lease of, or prescribe ConvaTec products or services. This definition includes, but is not limited to: a licensed physician, medical resident or fellow; non-physician healthcare practitioner, such as a nurse; medical student; and/or an institutional educational or healthcare facility, entity, or organization, including an academic medical center, as well as agents and employees for each of the above individuals or entities. An HCP is considered to be affiliated with an entity if the HCP is employed by, has staff privileges at, or otherwise has a position of influence with the entity.

ConvaTec developed this Manual to ensure that Third Parties adhere to the same ethical standards that we have established for our own employees and adhere to the laws of the countries in which we or they operate. Every Third Party is expected to comply with this Manual and any other compliance policies ConvaTec may send to you from time to time. This is a condition of maintaining a business relationship with ConvaTec. If any of the compliance requirements in this Manual conflict with the terms and conditions in a written agreement between the Third Party and ConvaTec, the terms of this Manual prevail. **In the event applicable laws, medical device industry association codes of conduct, or other regulations in a particular country or region are more restrictive, or require government approval of a transaction, then you must fully comply with the more restrictive requirements.** Any questions or concerns regarding this Manual or related inquiries may be directed to the ConvaTec Compliance Department by contacting the following email address: [ethics.compliance@ConvaTec.com](mailto:ethics.compliance@ConvaTec.com).

### ➤ General Principles

You are required to maintain your operations in **strict compliance with all applicable policies, codes, procedures, laws, regulations, ordinances, and any governmental requirements.** You will be responsible for obtaining all permits or licenses required by governmental authorities necessary for your business in relation to ConvaTec, including to import, distribute, market, and/or sell ConvaTec products. Policies, codes, and procedures governing our business relationship include, but are not limited to:

- This Manual;
- Your country's applicable medical device industry's code of conduct or ethics, if any, or any other applicable industry code (for example, AdvaMed or Eucomed);
- All applicable import and export control laws;
- ConvaTec's compliance training; and
- Other policies, procedures, and programs of ConvaTec, as are in effect or may be adopted by ConvaTec from time to time with notification to you.

In all dealings with the public and others, you will adhere to the highest standards of honesty, integrity, fair dealing, and ethical conduct.

Please ensure that all of your owners, employees, sub-distributors, agents, and representatives comply with all applicable laws and regulations. You and your owners, employees, sub-distributors, agents, and representatives involved in the ConvaTec business relationship agree to comply with this Manual, all training requirements, and any policies and procedures adopted by ConvaTec for which you are given notice. Please distribute – or otherwise make available – this Manual, and such Policies and trainings discussed above, to your owners, employees, sub-distributors, agents, and representatives working on ConvaTec matters.

## ➤ Representations

By agreeing to comply with ConvaTec's Third Party Policy you represent that:

### Anti-Corruption Representation:

- Neither you, nor any of your owners, employees, sub-distributors, agents, or representatives has been or is being:
  - investigated, fined, or convicted of violating the United States Foreign Corrupt Practices Act ("FCPA"); applicable national anti-bribery and corruption laws; and any other anti-bribery/corruption laws that may govern your activities in connection with your business relationship with ConvaTec;
  - investigated, fined, or convicted for violation of any medical device regulations; or
  - debarred, excluded, suspended, or otherwise declared ineligible from participation in any government health care program.

### Representation regarding Complaints by Enforcement Agencies:

- Except as specifically disclosed to ConvaTec in writing, neither you, nor any of your owners, employees, sub-distributors, agents or representatives has had a complaint filed against you by any enforcement agency, alleging either felony criminal acts, any crime relating to the practice of medicine, or any criminal acts related to fraud or theft.

### Notification:

- You, your owners, employees, sub-distributors, agents, or representatives shall notify ConvaTec immediately of any legal action, proceeding, or investigation relating to ConvaTec products or its operations or if any of the foregoing representations shall no longer be correct.

## GENERAL COMPLIANCE REQUIREMENTS

### ➤ Due Diligence

ConvaTec employees must take reasonable precautions to help ensure that ConvaTec's Third Parties observe applicable laws; the Code of Ethics and Business Conduct and the Global Policies on Business Conduct. As part of our continuing commitment to compliance with national anti-bribery laws, we have established a relationship with TRACE, an international business association of commercial intermediaries with a demonstrated commitment to transparent business practices. Thus, Third Parties will be subjected to due diligence screening prior to entering into a business relationship with ConvaTec.

Based on the information provided on the Third Party's questionnaire, TRACE will conduct an anti-bribery review, reputational clearance and verification of business reference contacts. There are absolutely no exceptions to this process. All Third Parties that intend to do business with ConvaTec must go through the TRACE due diligence process. Your compliance in completing the questionnaire from TRACE will provide ConvaTec with the confidence that the activities you undertake are in compliance with national and international anti-bribery obligations. The due diligence process will take place at the time of renewal, as well as the time of engagement. Please note that failure to submit accurate and complete responses on the TRACE questionnaire may delay the execution of the agreement with ConvaTec. In the event you have been certified by TRACE within the last year, please contact TRACE at [info@tracecheck.org](mailto:info@tracecheck.org) to release your due diligence results and/or certification to the designated ConvaTec representative.

### ➤ Training

With reasonable notice, ConvaTec may seek to provide Compliance trainings to your owners, employees, sub-distributors, agents and representatives who are involved in the ConvaTec business relationship. Of course, we welcome you to provide your own trainings to these parties. Please keep records of any such trainings, as it may be that your training reduces the need for a separate training conducted by ConvaTec.

As you retain new or additional employees, sub-distributors, agents, and representatives that will be involved in work for ConvaTec, you must train or otherwise inform the new employee(s) of the requirements set forth in this Manual. In some instances, ConvaTec may require you to notify us of any new employees hired to work on ConvaTec matters.

## ➤ Anti-Bribery

*ConvaTec prohibits all forms of bribery.*



Bribery is the provision of any payment or benefit to any person or entity in order to improperly influence the recipient or to gain an improper business advantage. **ConvaTec prohibits all forms of bribery.** Bribery is never an acceptable business practice and will not be tolerated by ConvaTec, including the offer, payment, solicitation, or acceptance of a bribe.

Third Parties should not offer, pay, request or accept any payment of money or anything of value which is:

- Intended to influence the judgment of the recipient in exercising his or her job responsibilities;
- Intended to secure preferential treatment or an advantage for the giver; or
- Intended as gratitude for the recipient having made a decision or acted in a way that benefited the giver improperly.

In order to ensure compliance with this Manual, as well as applicable laws, Third Parties should maintain complete and accurate books and records. All expenditures should be accurately reflected in the Third Party's financial records and all payments made should be properly authorized. No undisclosed or unrecorded accounts should be established for any purpose. False or artificial entries should not be made for any reason. Similarly, no accounts should be kept "off-book" in order to facilitate or conceal improper payments. Indeed, your contract with ConvaTec may allow for ConvaTec to inspect your books and records with respect to work done for ConvaTec or other items that ConvaTec may deem relevant in its discretion.

## ➤ Conflicts

During the term of the business relationship between you and ConvaTec, neither you, nor any of your owners, employees, sub-distributors, agents, or representatives will knowingly engage, directly or indirectly, in any activity which materially conflicts with the faithful performance of the services, duties, covenants, commitments, and obligations undertaken and to be performed by you pursuant to this Manual and/or your agreement with ConvaTec.

## ➤ Reporting

You must **immediately notify ConvaTec in writing of any violations or suspected violations of any law**, regulation, government health care program requirement, ConvaTec's Global Anti-Corruption and Bribery Policy, or your or ConvaTec's policies or procedures relating to legal or regulatory compliance matters. Notification may be made through the Compliance Helpline (discussed below).

To the extent allowed by applicable law, your reports will be treated as confidential and be used only for the purpose of addressing the specific problem reported. In order to facilitate reporting, ConvaTec has a Compliance Helpline. You can submit a report on the internet or via telephone as follows:

## Ethicspoint™

- ✓ Online through Ethicspoint, a user-friendly, web-based platform for filing whistleblower and other complaints:

**To submit inquiries or concerns online, please visit:**  
ConvaTec.ethicspoint.com

## NAVEX GLOBAL™

The Ethics and Compliance Experts

- ✓ By telephone using the toll-free hotline operated by our third-party helpline service, Navex. This service is available in all local languages.
  - Country-specific telephone numbers and dialing instructions can be found in the Global Helpline Directory, attached hereto as an Appendix.



## DISTRIBUTOR-SPECIFIC PROVISIONS

### ➤ Distributor Conflicts of Interest

You must **avoid at all times the impression that you are using family relationships to unduly influence purchasing decisions by HCPs or healthcare organizations**. You must therefore take great care when making sales to any individuals or entities with whom you have a personal relationship to ensure that you are not unfairly exploiting that relationship for a commercial benefit. Similarly, ConvaTec suggests that you take great care when hiring or engaging an employee who is an immediate family member of – or who has other familial relationships with – an HCP, or an employee, agent, or representative of any educational or health care organization.

If you do hire such an employee, you should consider the following factors, among others: (i) whether the employee has the requisite skills for the job, (ii) whether the employee is the most qualified applicant for the position, (iii) whether the employee's compensation is commensurate with his or her duties, and (iv) whether the HCP or employee of the health care organization was involved in recommending the employee.

Additionally, your employees are prohibited from promoting or selling ConvaTec products to any of the employee's immediate family members,<sup>2</sup> any entity where the immediate family member is in a position to influence or make decisions regarding ConvaTec products, or from receiving compensation for such sales. ***Note: You must also disclose to us if you become aware of any ConvaTec employee that may have an ownership or other financial interest in your company or its dealings with ConvaTec.***

### ➤ Extension of Relation to Further Parties (sub-distributors)

Generally, you may only appoint individual or entities to become your sub-distributor or sub-agent for ConvaTec products if the individual is your employee, or if the individual/entity is bound by a similar agreement with you to ensure compliance with your and ConvaTec's compliance policies. Under some circumstances, you may be required to obtain approval from ConvaTec before appointing sub-agents or sub-distributors. Throughout a sub-distributor's or sub-agent's engagement, you must ensure that such sub-distributor/sub-agent does not violate any terms and conditions of your agreement with ConvaTec. You and your entity will be individually responsible and liable for any obligations performed by a sub-distributor/sub-agent in connection with your agreement with ConvaTec.

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<sup>2</sup> For purposes of this Manual, an "immediate family member" means a person's husband or wife; birth or adoptive parents, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; or spouse of a grandparent or grandchild; or any person directly related or otherwise having a close relationship with you that could imply preferential treatment.

## ➤ Distributors and Tenders

A “tender” occurs when an organization requests bids from product manufacturers or their agents containing their best price for a certain amount and type of product. This occurs in the medical device industry most often when a university or hospital requests bids on a large amount of medical devices from several companies in order to get the lowest price for the products. The tender process often involves a government-owned entity.

**All tender submissions must comply with ConvaTec’s Anti-Corruption and Bribery Policy, Code of Ethics and Business Conduct, and applicable laws.** Tender submissions must not contain any boycott language (whether direct or indirect). Any expenses required to be paid in connection with the tender, outside of reasonable application fees (such as translation costs, mailing costs, etc.), must be reviewed by the ConvaTec Compliance Department prior to submission of the tender.

## ➤ Gray Market Reduction

Gray market sales are sales through unofficial or unauthorized channels. Gray market sales can expose ConvaTec and distributors to liability because: (1) products intended for sale in one country or region may not comply with all applicable regulations, particularly labeling requirements, in another country or region; (2) gray market products are subject to damage and tampering; and (3) gray market sales can result in violations of economic sanctions or export control laws.

**As consistent with local law and your written agreement with us, distributors may not sell any ConvaTec products in any country or region besides the one for which the products are intended. Please confer with your business contact at ConvaTec if you are unclear about the territorial scope of your distribution agreement with ConvaTec.** Distributors should not provide ConvaTec products to sub-distributors or customers who cannot adequately describe where the products will be used or who place unusually large orders without explanation. Products with improper labels or other indications of gray market sales should be reported to the ConvaTec Compliance Department.

## ➤ Import/Export Compliance

It is ConvaTec’s policy to comply with all applicable export control laws and economic sanctions, including, but not limited to, those administered by the U.S. Office of Foreign Assets Control (“OFAC”) and the Bureau of Industry and Security (“BIS”), the Federal Act on the implementation of International Sanctions (Embargo Act, EmbA) of Switzerland as well as the U.K. statutory instruments that incorporate sanctions and embargoes imposed by the E.U. and implement the U.K. Export Control Act 2002 (“ECA”) (collectively “Export Control Laws”).

**Third Parties may not engage in any transaction with the individuals, entities, and countries listed below without a valid license or exception:**

**Embargoed Countries**

OFAC's Country-Based Sanctions programs prohibit U.S. persons from engaging in virtually all transactions with individuals or entities located in embargoed countries. Embargoed countries include Cuba, Iran, North Korea, Sudan, and Syria. Business with certain embargoed countries may be permitted if appropriately licensed by OFAC.

**Governments of Embargoed Countries**

Third Parties may not engage in any transaction with governments of embargoed countries.

**Blocked Persons**

OFAC's List-Based Sanctions programs prohibit U.S. persons from doing business with certain individuals and entities in specific countries (e.g., Belarus, Ivory Coast, Zimbabwe), as well as individuals and entities participating in certain activities (e.g., narcotics trafficking, terrorism, and dealing in blood diamonds). These entities are included on OFAC's Specially Designated Nationals and Blocked Persons List ("SDN List").

**Foreign Sanctions Evaders**

OFAC's Foreign Sanctions Evaders Sanctions prohibit U.S. persons from doing business with individuals and entities that have: violated, attempted to violate, conspired to violate, or caused a violation of U.S. economic and financial sanctions on Syria or Iran; or facilitated deceptive transactions for or on behalf of persons subject to such sanctions.

**BIS Restricted Parties**

U.S. Bureau of Industry and Security ("BIS") is an office within the U.S. Department of Commerce responsible for administering and enforcing the Export Administration Regulations. BIS maintains a Restricted Parties list.

**Entities on SECO's Name List**

EmbA has formed the legal basis for the implementation of sanctions imposed by Switzerland, and is monitored by the State Secretariat for Economic Affairs ("SECO"). SECO maintains a prohibited name list.

**Sanctions Targets**

HM Treasury is responsible for the implementation and administration of international financial sanctions in effect in the UK, including maintaining the Consolidated List of Financial Sanctions Targets, which includes asset freeze targets designated by the United Nations, EU, and the UK.

You are required to verify all necessary documentation is obtained to import ConvaTec products under your agreement. Third Parties should consult their legal counsel or ConvaTec regarding specific applicable law and, if necessary, adopt their own policies to ensure compliance. For more detail on ConvaTec's policies, refer to the Global Policies on Business Conduct.

### ➤ **Distributor Books & Records**

As stated in written distributor agreements with ConvaTec, distributors must permit ConvaTec's internal and external auditors access to any relevant books, documents, papers, and records involving transactions related to ConvaTec or any other transactions that are deemed relevant in ConvaTec's discretion, subject to applicable data privacy and confidentiality laws. Distributors should ensure that their books and records are accurate in all transactions related to their business relationship with ConvaTec.

Particular care should be taken with discounts, rebates, credits, and similar transactions. ConvaTec encourages you to verify that there is a legitimate, commercially reasonable, and transparent reason for granting a customer a discount, rebate, or credit. You should retain written documentation memorializing the specific terms and conditions of any discount, rebate, or credit and the means by which any such price reduction will be earned or applied (for example, as a purchase-specific volume-based discount reflected in the invoice price, a volume-based rebate to the customer based on purchases made over time, or a volume-based credit earned on purchases made).

## SPECIFIC COMPLIANCE REQUIREMENTS FOR INTERACTIONS WITH HCPS OR GOVERNMENT OFFICIALS

### ➤ Meals, Hospitality, and Travel

From time to time, a Third Party may be in the position of providing hospitality to an HCP or Government Official.<sup>3</sup> This could include a one-on-one business lunch or dinner or a larger conference with many attendees. Such occasions should always be professional in nature and principally concern the presentation of product education, promotional material, or business information, or other business needs.

As stated earlier in this Manual, if applicable laws, codes of conduct, or other regulations in a particular country or region are more restrictive on this subject, or require government approval or disclosure of the interaction, you must then fully comply with the more restrictive requirements.

Hospitality may only take the form of meals, receptions, or similar events within a business context. **No entertainment or similar activities are permitted** (e.g. theater, sporting events, museums, golfing, skiing, massages, dinner cruises, hunting, leisure or vacation trips, and city tours).

Where ConvaTec will be paying (in whole or in part) for an HCP or Government Official's travel or accommodations, you may only make such arrangements after receiving approval from ConvaTec's Compliance Department. If ConvaTec will not be paying for the travel or accommodations (i.e., you will be paying for it yourself), you need not obtain ConvaTec's approval in advance, though the arrangements may be the subject of periodic monitoring and auditing by ConvaTec for compliance with this Manual.

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<sup>3</sup> "Government Officials" include:

- 1) Any officer or employee of a government, its armed forces, or any department, agency, or instrumentality of a government, such as a state-owned or -controlled company;
- 2) Any person acting in an official capacity for or on behalf of that government or department, agency, or instrumentality;
- 3) Any official, employee, or person acting on behalf of a public international organization, such as the European Union, the Red Cross, or the World Health Organization;
- 4) Any officer or employee who is remunerated either directly or indirectly by a government, or any department, agency, or instrumentality of a government, including without limitation an HCP;
- 5) Any HCP working in, on behalf of, or otherwise affiliated with a government healthcare facility, institution, university or hospital;
- 6) A candidate for a political office; and
- 7) Any relative of the persons listed above.

Any meals, hospitality, business travel, or lodging must meet all of the following criteria (for more detail, consult the ConvaTec Global Policies on Business Conduct):

- It is incidental to a bona fide business purpose and each person attending must have a legitimate business need (*i.e.*, you cannot provide a meal for the entire staff of an office when all the staff do not have a business purpose to participate in the meeting/meal. Similarly, spouses and immediate family members cannot participate in meetings/meals without a business justification);
- It is modest, reasonable, and infrequent;
- It is not provided as an incentive or reward for the purchase, prescription, use, order, or recommendation of ConvaTec's products;
- It does not create the appearance of impropriety;
- For meals and hospitality events, a Third Party employee is present for the entire duration of the event; for travel, the duration of the trip does not include days beyond which the HCPs are engaged in the Third Party business-related activities; and
- The amount spent is in line with ConvaTec-issued guidance on how much can be spent on meals, hospitality, and travel in your particular region.

You may not purchase alcoholic beverages for HCPs or Government Officials outside of a legitimate business meeting. The purchase of alcoholic beverages for HCPs at a legitimate business meeting must be limited and controlled.

Similarly, the purchase of alcoholic beverages for any non-HCP customers must be limited and controlled.

### ➤ Gifts

**No gifts should be given to HCPs, Government Officials, customers, sub-distributors, or their family members or staff.** This includes items such as baked goods, flowers, candy, gift baskets, holiday gifts, gift cards, raffle prizes or collective gifts, thank you gifts, or gifts to recognize a significant event (birthday, anniversary, birth, funeral, etc.). Additionally, this general prohibition applies to non-educational branded or unbranded promotional items, such as mugs, pens, notepads, stress balls, key fobs, mousepads, and any other item bearing the ConvaTec name or product logo.

However, there are exceptions to this rule. Specifically, you may provide gifts or promotional items to HCPs, Government Officials, customers, or sub-distributors if doing so is expressly permissible under: (a) local law; or (b) the governing industry association's code of ethics. For example, the Eucomed Code of Ethical Business Practice, applicable in many European countries, expressly allows for certain inexpensive items (e.g., stationery items, calendars, etc.) to be provided to HCPs under some circumstances.

Additionally, you may provide gifts or promotional items if approved in advance by ConvaTec's Compliance Department. **In any case, if you plan to provide a gift or promotional item that is expressly permissible under local law or the governing industry association's code of ethics, you must obtain advance approval from ConvaTec's Compliance Department before providing the gift or promotional item.**

Where local laws, regulations, or trade association guidelines explicitly permit, you may provide an educational item (e.g., a textbook or anatomical model) to HCPs, provided the item benefits patients or serves a genuine educational function. The provision of educational items is subject to the following restrictions:

- The educational item is given on an infrequent basis and not upon request of an HCP, customer, or sub-distributor.
- The educational item is provided unconditionally, absent any explicit or implicit agreement that the individual will be expected to purchase, use, order, or recommend ConvaTec's products, or that the educational item represents a reward for past use, prescription, orders, or recommendations of ConvaTec's products.
- The educational item may not be provided in a medium that can be easily diverted for personal, non-educational alternative use such as an iPad/Tablet, DVD player, or MP3 player.
- The educational item is not provided in the form of cash or cash equivalents (e.g. gift cards to purchase educational items).
- The educational item is not purchased with the use of cash or cash equivalents (i.e., gift cards), and an itemized receipt is obtained at the time of purchase for the educational item.
- The educational item is not provided to the spouses, friends, or relatives of HCPs, Government Officials, customers, or sub-distributors, unless such party may, in their own right, receive an educational item in accordance with these standards.
- The educational item must not create the appearance of impropriety.

Gifts to HCPs can create substantial compliance risk under applicable laws. As stated above, **no entertainment or recreation may be provided to HCPs, Government Officials, customers, or sub-distributors. There are no exceptions to this rule.**

**No entertainment or recreation may be provided at any time.**



## ➤ Consulting & Speaking Arrangements

At times, you may wish to enter into service agreements with HCPs for product development services, evaluation services, research services related to ConvaTec products, or speaking services. Arrangements for such services must not be used to induce or reward the purchase, use, or recommendation of ConvaTec products. If you arrange any HCP services in relation to ConvaTec products, please document the services and ensure that they have a bona fide business purpose. You may contact ConvaTec to help provide appropriate guidelines for such contractual arrangements.

If ConvaTec is sponsoring or co-sponsoring the agreement with you, you must obtain approval from ConvaTec prior to entering into the agreement. If ConvaTec will not be sponsoring the agreement (i.e., you will be paying for it yourself), you need not obtain ConvaTec's approval in advance, though the agreement may be the subject of periodic monitoring and auditing by ConvaTec.

From time to time, ConvaTec may request that you identify an HCP with specific expertise for a potential speaking or consulting arrangement directly with ConvaTec due to your knowledge of HCPs within your territory. Under no circumstances should you consider sales or potential sales in identifying an HCP with qualifications and expertise. You must not contact or make any commitments to an HCP regarding ConvaTec's request; all contacts regarding such arrangements will come from ConvaTec.

## ➤ Educational Grants, Sponsorships, & Charitable Donations

Educational grants, sponsorships and charitable donations that are made on behalf of ConvaTec must have a bona fide educational, business, or charitable purpose and may not be promised or given to induce or reward the purchase, use, or recommendation of ConvaTec products. All such expenditures should be accurately recorded in your books and records. If ConvaTec will be paying for the grant, sponsorship, or donation (in full or in part), the expense must be preapproved by ConvaTec. If ConvaTec will not be paying for the arrangement (i.e., you will be paying for it yourself), you need not obtain ConvaTec's approval in advance, though the arrangement may be the subject of periodic monitoring and auditing by ConvaTec. Relatedly, you should not commit to making any grants, sponsorships, or donations on ConvaTec's behalf without ConvaTec's permission.

## ➤ Samples

While samples are an important tool in product trial, training, education, and sales, it is imperative that product samples be provided in accordance with the policy outlined below in order to avoid abuse, comply with regional and local law, and avoid the appearance of impropriety.



**Samples of ConvaTec product must not be offered as an improper inducement or reward to purchase, dispense, prescribe, use, order, or recommend ConvaTec products, or otherwise to improperly benefit ConvaTec's business activities.**

Evaluation and demonstration samples may be provided at no charge to HCPs and patients to facilitate the safe and effective use of ConvaTec products and technologies in a manner that is consistent with the indication for use in the product labeling, and increase awareness of a product's technology and use. Products used for demonstration purposes should be properly disposed of after a demonstration, unless the product maintains its integrity for further use or demonstration. The number of product samples given to an individual HCP or patient must be appropriate for the evaluation or demonstration activity only.

Samples may never be provided where there is reason to believe samples will be sold, traded, bartered, returned for credit, or utilized to seek reimbursement. HCPs may never seek payment for the provision of samples from a patient, third-party payor (e.g., insurance company), or any other entity. Please communicate to recipients that samples cannot be sold, traded, bartered, returned for credit, or utilized to seek reimbursement.

Third Parties must closely track their disposition of samples and report this information back to the appropriate business contact at ConvaTec.

## PRODUCT SAFETY

**It is important not to promise ConvaTec customers that ConvaTec will perform specific tasks or provide specific types of reports prior to ConvaTec's review of an issue.**



### ➤ Complaint Procedures

The purpose of the Complaint procedure is to establish a timely and efficient method of handling, reporting, and returning product complaints to ConvaTec for investigation. ConvaTec defines a "Complaint" as any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of any device or product of ConvaTec or any subsidiary. The following protocol must be followed by a Third Party who is made aware of a Complaint by any written, oral, electronic, or other communication:

- 1) Within 24 hours, you must inform ConvaTec of a Complaint by contacting the following email address: [wwps.complaints@convatec.com](mailto:wwps.complaints@convatec.com)
- 2) Please gather as much information about the Complaint as possible and include such information when contacting the email address above. Gather as much of the following information as possible:
  - a. Identity of the person making the Complaint
  - b. Details of the underlying incident or issue
  - c. Any injury or damage related to the underlying incident or issue
  - d. Place of occurrence of the underlying incident or issue
  - e. Date of occurrence of the underlying incident or issue
- 3) For Complaints that are generated from inside the United States, please call ConvaTec's Customer Interaction Center at 1-800-422-8811 **within 24 hours**.

### ➤ **Post-Market Field Actions**

You must comply with all ConvaTec post-market field actions, commonly referred to as "recalls." A post-market field action can be executed through either a (1) "Removal," in which a product is removed from the market and sent back to a designated site, or (2) through a "Correction," in which a product is not removed from the market and is instead corrected in place (referred to as a Field Safety Notice (FSN)). Only ConvaTec can approve the initiation of a post-market action.

You will be notified in writing through a recall notice and response form when ConvaTec has made a decision to conduct a post-market action.

We ask that you follow these required guidelines when responding and/or initiating a post-market field action:

- Follow all instructions provided in the recall notification and response form and promptly provide responses, response forms, and return of affected product as indicated in the recall notice.
- The recall notification will provide you with the proper instructions to follow if you have further distributed the affected recalled product. You must immediately notify each of your consignees of the recall action. A consignee is considered to be any customer to whom you have distributed the affected product. Examples of consignees include health care facilities, agents, sub-contactors, wholesalers, a retailer, or a direct consumer/patient.
- The recall notification and response form will provide the instructions to be followed if the affected recall product is to be removed from the consignees' location. Under a recall, all affected product quantities or absence of affected product must be documented on the recall response form. The completed recall form and any affected product must be returned to the designation indicated in the recall notification.

- Various reports will be required from you when reporting on the completeness for notifications of consignees and your progress in closing your requirements to the recall. These requests for reports will be communicated to you through your ConvaTec representative and/or a ConvaTec recall coordinator.
- You are expected to train and document the training of your employees, sub-distributors, agents, and representatives on the above requirements for initiating and completing a recall.

## Appendix

### Operator Assisted Calls Global Helpline Directory

Updated: October 2015

Helpline related inquiries or reports may be submitted 24 hours/day, 7 seven days/week, via internet to [ConvaTec.ethicspoint.com](http://ConvaTec.ethicspoint.com); for operator assisted calls, please follow the process below.

#### Navex Global - Line Types and Dialing Steps for Domestic US, International Toll-Free Service (ITFS), Global Inbound Service (GIS): One step dialing

1. From an outside line, dial the number for your location.
2. The call will be answered in the languages selected. To continue your call in another language, options will be available to select.

\* Please note waiting times to be connected to an Interpreter are dependent on availability.

#### World Wide Connect: Two step dialing

For all two-step dialing, first dial your corresponding access code and when prompted, enter the 855 number. According to how the lines are provisioned within each country, different in-country numbers may be required for each carrier. When placing a call from that country, dial the number specific to your carrier. (There is no guarantee the call will connect if you call one of the other carriers' numbers).

1. From an outside line, dial the AT&T Direct Dial Access® for your location.
2. At the prompt dial 855-357-8473.
3. The call will be answered in the languages selected. To continue your call in another language, options will be available to select.

\* Please note waiting times to be connected to an Interpreter are dependent on availability.

#### Reverse Charge Calls, Collect Calls: Two step dialing

1. From an outside line contact your local operator.
2. Request a reverse charge or collect call, to the number for your location.
3. All reverse charge or collect calls will be accepted by the Contact Center using an automated English message.

Country	Type of line	First Step	Second Step
<b>Argentina</b> 	ITFS (one step dialing)	<b>0800-444-3463</b>	
<b>Australia</b> 	WorldWide Connect (two step dialing)	<b>1-800-551-155 (Optus) 1-800-881-011 (Telstra)</b>	<b>855-357-8473</b>
<b>Austria</b> 	WorldWide Connect (two step dialing)	<b>0-800-200-288</b>	<b>855-357-8473</b>
<b>Belarus</b> 	WorldWide Connect (two step dialing)	<b>8^800-101</b>	<b>855-357-8473</b>
<b>Belgium</b> 	WorldWide Connect (two step dialing)	<b>0-800-100-10</b>	<b>855-357-8473</b>
<b>Brazil</b> 	WorldWide Connect (two step dialing)	<b>0-800-890-0288 0-800-888-8288 (cell)</b>	<b>855-357-8473</b>
<b>Canada</b> 	US Dialing Plan (one step dialing)	<b>855-357-8473</b>	

<p>Chile</p> 	WorldWide Connect (two step dialing)	800-800-311 (Easter Island) 800-800-312 (Easter Island - Spanish) 800-360-311 (ENTEL) 800-360-312 (ENTEL - Spanish) 800-800-288 (Telefonica) 800-225-288 (Telmex - 800)	855-357-8473
<p>China</p> 	GIS (one step dialing)	400-880-1324	
<p>Colombia</p> 	WorldWide Connect (two step dialing)	01-800-911-0010 01-800-911-0011 (Spanish)	855-357-8473
<p>Czech Republic</p> 	WorldWide Connect (two step dialing)	00-800-222-55288	855-357-8473
<p>Denmark</p> 	WorldWide Connect (two step dialing)	800-100-10	855-357-8473
<p>Dominican Republic</p> 	Collect (one step dialing)	Contact Local Operator	503-444-4979
<p>Ecuador</p> 	WorldWide Connect (two step dialing)	1-800-225-528 1-999-119 (Spanish)	855-357-8473



<p><b>Egypt</b></p> 	WorldWide Connect (two step dialing)	2510-0200 (Cairo) 02-2510-0200 (Outside Cairo, cellular throughout Egypt)	855-357-8473
<p><b>Finland</b></p> 	ITFS (one step dialing)	0800-917-698	[REDACTED]
<p><b>France</b></p> 	ITFS (one step dialing)	0800-905-991	
<p><b>Germany</b></p> 	WorldWide Connect (two step dialing)	0-800-225-5288	855-357-8473
<p><b>Greece</b></p> 	WorldWide Connect (two step dialing)	00-800-1311	855-357-8473
<p><b>India</b></p> 	WorldWide Connect (two step dialing)	000-117	855-357-8473
<p><b>Ireland</b></p> 	WorldWide Connect (two step dialing)	1-800-550-000 00-800-222-55288 (UIFN)	855-357-8473

<p>Italy</p> 	WorldWide Connect (two step dialing)	800-172-444	855-357-8473
<p>Japan</p> 	ITFS (one step dialing)	00531-11-0364 (KDD) 0066-33-830593 (Softbank Telecom) 0034-800-600213 (NTT)	
<p>Republic of Korea</p> 	WorldWide Connect (two step dialing)	00-309-11 (Dacom) 00-729-11 (Korea Telecom) 00-369-11 (ONSE) 550-2USA (US Military Bases Dacom) 550-HOME (US Military Bases Korea Telecom)	855-357-8473
<p>Luxembourg</p> 	WorldWide Connect (two step dialing)	800-201-11	855-357-8473
<p>Malaysia</p> 	ITFS (one step dialing)	1-800-817-838	
<p>Mexico</p> 	ITFS (one step dialing)	001-855-420-4975	
<p>Netherlands</p> 	WorldWide Connect (two step dialing)	0800-022-9111	855-357-8473



<p>New Zealand</p> 	WorldWide Connect (two step dialing)	000-911	855-357-8473
<p>Norway</p> 	ITFS (one step dialing)	800-12181	
<p>Peru</p> 	WorldWide Connect (two step dialing)	0-800-70-088 (Americatel) 0-800-50-288 (Telephonica) 0-800-50-000 (Telephonica - Spanish)	855-357-8473
<p>Poland</p> 	ITFS (one step dialing)	00-800-151-0068	
<p>Portugal</p> 	WorldWide Connect (two step dialing)	800-800-128	855-357-8473
<p>Russia</p> 	WorldWide Connect (two step dialing)	8^10-800-110-1011 363-2400 (Moscow) 8^495-363-2400 (outside Moscow) 363-2400 (St. Petersburg) 8^812-363-2400 (outside St. Petersburg)	855-357-8473
<p>Singapore</p> 	WorldWide Connect (two step dialing)	800-011-1111 (SingTel) 800-001-0001 (StarHub)	855-357-8473

<p><b>Slovak Republic</b></p> 	WorldWide Connect (two step dialing)	0-800-000-101	855-357-8473
<p><b>South Africa</b></p> 	ITFS (one step dialing)	0800-981-840	
<p><b>Spain</b></p> 	WorldWide Connect (two step dialing)	900-99-0011	855-357-8473
<p><b>Sweden</b></p> 	WorldWide Connect (two step dialing)	020-799-111	855-357-8473
<p><b>Switzerland</b></p> 	WorldWide Connect (two step dialing)	0-800-890011	855-357-8473
<p><b>Taiwan</b></p> 	WorldWide Connect (two step dialing)	00-801-102-880	855-357-8473
<p><b>Thailand</b></p> 	ITFS (one step dialing)	001-80011-002-9734	

<p>Turkey</p> 	WorldWide Connect (two step dialing)	0811-288-0001	855-357-8473
<p>UK &amp; NI</p> 	ITFS (one step dialing)	0808-234-2300	
<p>United States</p> 	US Dialing Plan (one step dialing)	855-357-8473	