

Annex I – Dealer Quality Requirements

These requirements apply to the Distributor as Logistic platform, T1 Dealers and T2 Dealers engaged by the Distributor.

所有代理商和经销商，包括物流平台，一级经销商和二级经销商等，都适用以下质量要求。

Distributors/Dealers shall comply with all applicable Medical Device Regulations in China, in addition to the quality requirements stated below.

代理商/经销商应遵守中国范围内所有适用的医疗器械法律法规，并且满足下面规定的质量要求。

These requirements apply to all products supplied by BSC to distributors/dealers, regardless of when transfer of ownership happens.

这些要求适用于所有由 BSC 供给代理商/经销商的产品，无论产品物权的转移是在何时完成，代理商/经销商都应能满足下面的要求。

A) Product Storage: Distributor/Dealer is required to store products in accordance with applicable product labeling statements and within an environment that prevents any of their characteristics from being altered until delivered to the customer. The minimum storage requirements for Boston Scientific products include the following:

产品储存: 我们要求代理商/经销商按照产品相应的标签内容储存产品，防止产品特性改变，直至产品发给客户。波士顿科学产品存储最小要求如下：

- Products must be stored within a secure, clean, pest free environment to prevent product tampering or contamination.
产品必须储存在安全、清洁、无虫害的储存场所，防止产品污染。
- Access to the product storage location must be limited to only those personnel authorized by Distributor/Dealer.
只有代理商/经销商授权人员才能进入产品储存场所
- The product storage location must be capable of maintaining the environmental conditions specified on the product label and/or DFU which defined by Boston Scientific. Should environmental conditions deviate from these requirements, Distributor/Dealer shall contact Boston Scientific for guidance. Distributor/Dealer shall report to Boston Scientific the details of the deviation including the duration(s) and the environmental condition(s) of the period(s) of concern. Boston Scientific shall provide instructions regarding disposition of the Product.
If there is special temperature and humidity storage requirements, according equipment should be placed to control and monitoring of the temperature and humidity of products
产品存储场所必须能够维持在产品标签和产品说明书上指明的波士顿科学确定的环境条件。若环境条件偏离这些要求，代理商/经销商应联系波士顿科学寻求指导。代理商/经销商应向波士顿科学报告偏离的详细信息，包括持续时间及所述期间的的环境条件。波士顿科学应提供有关产品处置的指导。如有特殊温湿度储存要求的医疗器械，应当配备有效调控及监测温湿度的设备或仪器。
- Distributor/Dealer shall have a process to prevent expired, non-conforming, and/or quarantined Products from being sent to final customers. Boston Scientific reserves the right to provide instructions to Distributor/Dealer regarding such Product.
代理商/经销商应具备防止过期、不合格及/或隔离产品被送至最终客户的程序。波士顿科学有权向代理商/经销商提供有关此类产品的指导。
- Handling and stacking medical devices shall be in accordance with the packaging and labeling requirements of the products, to avoid damage of medical device packaging.
搬运和堆垛医疗器械应当严格按照包装标识要求规范操作，堆垛高度符合包装图示要求，避免损坏医疗器械包装；
- Storage of medical device could adopt color management according to product quality state,

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quarantined area and return area is yellow, the qualified product area is green, shipping area is green, and nonconformance product area is red.

在库房储存医疗器械，可以按产品质量状态实行色标管理，待验区为黄色、合格品区为绿色、发货区为绿色、不合格品区为红色、退货区为黄色。

- For products returned from customers, Distributor/Dealer shall verify that the product and/or packaging are not damaged, tampered with or altered in any way, expired, non-compliant with applicable Regulations or otherwise non-conforming before re-stocking and re-distributing them.

针对客户退回的产品，在实物退回之前，代理商/经销商应确认在任何情况下产品和/或包装无损坏，篡改或变更，过期，不符合当地法律法规要求或其他不符合项的情况。

- B) Product Traceability:** Distributor/Dealer is required to maintain records to ensure the traceability of Boston Scientific products in accordance with applicable regulatory requirements, and to provide Boston Scientific or its authorized agents or representatives with reasonable access to such records.

产品追溯性: 代理商/经销商须按照适用的法律法规监管要求保持记录，以确保对波士顿科学产品的追溯性，并向波士顿科学或经其授权的代理人或代表提供查阅此类记录的合理权限。

Distributor/Dealer is required to maintain a complete and current list of all customers who have purchased or consigned products from Distributor/Dealer (such as hospitals, doctors, and/or patients), to include the following (as applicable):

代理商/经销商须保持有关从代理商/经销商处采购或寄存产品的全部客户（例如医院、医生及/或患者）的完整而最新的清单，包括（适用的）下列信息：

- the dates of such purchases or consignment
采购或寄存产品的日期
- Customer name, address and at least one contact detail (telephone number, fax number, and/or email address)
客户名称，地址及包括至少一种联系方式（联系电话，传真号码，和/或邮箱地址）
- date of implant or attempted implant of active implantable medical devices and their accessories
植入或试图植入有源植入性医疗器械及其配件的日期，
- the quantity
数量
- the model number (as identified on the product label)
产品号（见产品标签）
- the lot and / or serial numbers (as identified on the product label)
批号及/或序列号（见产品标签）
- UPNs /GTIN (as identified on the product label)
规格型号/GTIN（见产品标签）

Distributor/Dealer shall maintain current and historical traceability records for programmers (if selling the CRM portfolio) and other equipment locations and movements, in addition to the applicable requirements above (If applicable).

针对程控仪，代理商/经销商应保存当前及历史的追溯记录（如果是销售的 CRM 产品），以及其他设备位置，周转，还有以上其他适用的要求(如适用)。

If products are consigned, the units consumed at the account must be reconciled. 如果产品是寄

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存的，必须核对该客户产品使用的数量

Distributor/Dealer should regular check inventory counting and keeps BSC DMS updated.
代理商/经销商应定期确认库存盘点并保持波士顿科学 DMS 系统更新。

- C) **Products receiving and check:** Distributor/Dealer should do visual check of receiving products (include return products) before deliver products to stock. The visual check criteria will be listed in items P).

产品接收和检查: 代理商/经销商应在接到产品（包括退货产品）后进行产品外观检查。具体检查标准已列在 P) 中。

- D) **Implant Reporting (If applicable) :** Distributor/Dealer shall submit timely implant registration forms to Boston Scientific for all active implantable medical devices and their accessories, when applicable in the territory.

植入报告（如适用时）: 代理商/经销商应及时将关于所有有源植入性医疗器械及其附件的植入登记表递交给波士顿科学，如当地监管部门要求时。

- E) **Complaint Reporting:** Distributor/Dealer is required to promptly forward to Boston Scientific any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a device (hereinafter referred to as 'complaint') within two business days.

投诉报告: 代理商/经销商须在收到声称和器械的识别、质量、耐用性、可靠性、安全性、有效性或性能等相关瑕疵的任何书面的、电子的或口头的沟通（下文简称“投诉”）后两个工作日内，及时将其转呈波士顿科学。

- A complaint notification form will be provided to Distributor/Dealer by Boston Scientific and must be completed to document each complaint. Additionally, any ancillary documentation that may facilitate the complaint investigation process should also be attached, particularly if the product is not available for return.
波士顿科学将向代理商/经销商提供投诉通知表，代理商/经销商必须填写，记录每个投诉。此外，还须随附何便于开展投诉调查程序的辅助文件，在不能返回产品的情况下尤其必要。
- Distributor/Dealer is required to cooperate fully with Boston Scientific in dealing with customer complaints, and take such action to resolve such complaints as may be reasonably requested by Boston Scientific.
代理商/经销商须在处理客户投诉时充分配合波士顿科学，并按照波士顿科学的合理请求采取措施解决此类投诉。
- In cases where additional complaint information is required, at least three due diligent attempts must be performed and documented by Distributor/Dealer to collect the information, as requested by Boston Scientific. Should requested information not be available, Distributor/Dealer shall document the reason it is unavailable.
若按照波士顿的要求，需要更多的投诉信息，则代理商/经销商须执行并记载至少三次的尝试，以收集信息。若无法获得所需信息，代理商/经销商应记录无法获得的原因。
- Products subject to complaints should be returned to Boston Scientific following appropriate process as detailed in Section F (Handling Biohazardous or Hazardous Product Returns).
被投诉的产品应按照适用的流程返回给波士顿科学（具体参考 F 部分）。
- In cases where the customer has indicated the product is available but has not returned it, Distributor/Dealer shall document at least three due diligent attempts to retrieve the product.
若客户表明可以获得产品但却未返回，则经销商应记载至少三次尽职调查尝试，以索回产品。

- F) **Handling Biohazardous or Hazardous Product Returns:** Biohazardous and hazardous product returns must be handled in the following manner, as directed by Boston Scientific:

生物危害或者危险产品返回: 生物危害及危险产品的返回必须遵循波士顿科学的指导, 按照如下方式处理:

Active Implantable Medical Devices and their Accessories:

有源植入性医疗器械及其配件:

All active implantable medical devices and their accessories that have been used in a procedure or have been implanted shall be considered bio hazardous.

在手术中用过的或已植入的全部有源植入性医疗器械及其配件应视为生物危害产品。

- Products must not be decontaminated, disinfected, or sterilized before returning, as doing so may interfere with product testing and the product investigation.
产品退回前不能被净化, 消毒或者杀菌, 可能会影响产品测试和产品调查分析。
- These products must be returned in biohazard controlled packaging and under safe handling controls.
产品必须使用危害控制包装返回且在安全操作下执行。

Other Medical Devices:

其他医疗器械

- Products(*) must be accompanied by a disinfection certificate, even if the devices have not been used, or
产品(*)必须附有消毒证明, 即使产品没有使用, 或者
- Products (*) must be returned in biohazard controlled packaging and under safe handling controls.
产品(*)必须使用危害控制包装返回且在安全操作下执行。

(*) No disinfection certificate is needed for Medical Equipment

(*)医疗设备不需要消毒证明

Hazardous Product Returns (i.e. explosives):

- Boston Scientific will provide instructions for appropriate handling of these returns.
波士顿科学将提供所有适用的产品返回的操作指导。

- G) **Vigilance or other Medical Device Adverse Event Reporting:** Distributor/Dealer shall establish vigilance or other Medical Device Adverse Event Reporting system and effective execution according to China Regulation requirement. Distributor/Dealer shall inform Boston Scientific with sufficient anticipation prior to the vigilance or any other medical device adverse event reporting to their territory.

警戒系统或其他医疗器械不良事件报告: 代理商/经销商应按照法规要求, 建立不良事件制度并有效执行。当代理商/经销商上报警戒系统或其他医疗器械不良事件给当地监管部门之前, 应当告知波士顿科学, 以确保其充分参与。

- H) **Recalls and Other Field Actions:** If Boston Scientific initiates a recall or other field action for any products (including those sold by previous distributor(s)/dealer(s) or by Boston Scientific), Distributor/Dealer is required to implement such recall or other field action (including location and retrieval of the recalled product) in accordance with the instructions provided by Boston Scientific.

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The minimum requirements for managing recalls and other field actions affecting Boston Scientific products includes the following:

召回和其他现场行动：如果波士顿科学启动有关任何产品（包括先前已由代理商/经销商或波士顿科学售出的产品）的召回或其他现场行动，代理商/经销商须按照波士顿科学提供的说明实施此类召回或其他现场行动（包括被召回产品的位置及索回）。

- Recalls and other field actions must be acted upon immediately by Distributor/Dealer after receiving the notification packet from Boston Scientific. An acknowledgement of the receipt of the field action notice must be sent to Boston Scientific.
代理商/经销商在收到波士顿科学的通知文件后应立即行动，开展召回及其他现场行动。经销商必须向波士顿科学发送收到现场行动通知的确认书。
- Distributor/Dealer must follow the instructions contained in the notification packet and ensure that actions are carried out in accordance with the timeframe specified.
代理商/经销商必须遵守通知文件中包含的指南，确保在指定的时限内完成行动。
- Where directed in the notice, Distributor/Dealer must retrieve products from the following applicable locations:
若通知中有说明，代理商/经销商必须从下列适用位置取回产品
 - Distributor/Dealer warehouse(s) inventories
代理商/经销商仓库库存
 - In-transit from Boston Scientific to Distributor/Dealer
波士顿至代理商/经销商的转运途中
 - All inventory in control of the Distributor/Dealer
所有代理商/经销商控制下的库存
 - Customer locations: whether sold, consigned or samples
客户地点：不论是出售产品、寄存产品还是样品。
- At least three due diligent attempts must be performed and documented to try to retrieve products from customers.
必须执行并记载至少三次尽职尝试，以尝试从客户处取回产品。
- Once all product retrieval actions have been completed, the recalled stock must be reported to Boston Scientific using the verification form contained in the notification packet. (Note: the quantities documented on the verification forms must match the units physically returned to Boston Scientific.)
一旦完成全部的产品索回行动，即须使用通知包中的验证确认表向波士顿科学报告被召回的现货。（注：在验证确认表中记载的数量必须与返回波士顿科学的实物产品数量相符。）
- The units must be returned to Boston Scientific following the instructions contained in the notification packet.
必须按照通知文件中记载的说明将产品返回给波士顿科学。
- Distributor/Dealer shall inform Boston Scientific within a reasonable period of time of any changes to the recall and other field action requirements within the territory.
代理商/经销商必须在合理的期限内告知波士顿科学，对于召回行动的任何变更和当局的其他召回要求。

- I) NFHU Units (If applicable) :** NFHU Units (non-sterile, not for human use) shall be used by Distributor/Dealer for demonstration purposes only and shall not be given to final customers. Nonfunctional implantable generators that do not contain a battery are the only demos that can be given to customers.

不能用于人体的产品（如适用）：代理商/经销商应将演示产品（非无菌、不可使用于人体）仅用

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于展示，而不得用于临床实验或环境。

NFHU shall not be given to final customers, except in the two following situations:

NFHU 产品不能提供给最终客户，以下两种情况除外：

- NFHU products used in animal studies or in vitro models can be given to customers provided that the products are destroyed in the presence of a Distributor/Dealer employee, or that the customer signs a statement that agrees saying that the NFHU products will be destroyed.

NFHU 产品用于动物实验或者体外测试，可以提供给客户，即产品在代理商/经销商人员在场情况下破坏，或者客户签字确认 NFHU 产品将会被破坏使用。

- Non-functional, non-sterile implantable pulse generators that do not contain a battery (weighted titanium).

非功能性且非无菌的可植入式脉冲发生器不能含有电池

- Distributor/Dealer shall not convert product from complaint, recall and non-conforming products into NFHU units.

NFHU 产品应有波士顿科学提供，代理商/经销商不可以将客户抱怨产品，召回产品或者不合格品转化为 NFHU 产品。

- Distributor/Dealer shall not convert into NFHU active implantable or medical equipment products from inventory into NFHU without prior written approval by BSC.

在没有波士顿科学书面批准下，代理商/经销商不可以将任何库存下的有源植入性或者医疗设备产品转化成 NFHU 产品。

- NFHU Units must be labeled or engraved with at minimum the following text; “Not for Human Use – Non sterile” and the sterile barrier must be broken unless if used with animals.

NFHU 产品必须标记为或者刻有至少以下内容：“Not for Human Use – Non- sterile”以及无菌带已经被破坏，除非用于动物身上。

J) Label Control: BSC is responsible for ensuring that product labeling meets local laws.

Distributor/Dealer can't attach any extra label unless be authorized by BSC China.

波士顿科学确保产品标签符合当地法律。代理商/经销商在非波士顿中国授权的情况下不可以添加额外任何标示。

K) Training: The Distributor/Dealer is responsible for maintaining Quality training records that are complete and accurate, including the name(s) of the trainer(s), the date of the training, training content, full names of attendees, if not trained by BSC personnel.

培训：对于非波士顿科学人员给予的培训，代理商/经销商有责任确保质量培训记录的完整性和准确性，包括培训人员，培训时间，培训内容，参加人员名称。

- Distributor/Dealer's employees directly engaged in selling the Products who have not previously attended a Boston Scientific technical training seminar will attend such a seminar or will be trained by Distributor/Dealer in a program approved by Boston Scientific within a reasonable period of time after the commencement of their involvement in the sale of the Products.直接参与产品销售、先前尚未参加过波士顿科学的技术培训研讨会的代理商/经销商员工将在开始参与产品销售后的合理期限内，参加此类研讨会，或由代理商/经销商以经过波士顿科学批准的方案进行培训。

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- The Distributor/Dealer shall also train sub- distributor(s)/ sub-dealer(s), maintaining accurate and complete training records.
代理商/经销商应培训所属下级代理商/经销商，确保培训记录的准确和完整性。
- Quality training records shall be provided to BSC before Distributor/Dealer appointment according to China GSP requirement.
如有要求，根据中国 GSP 法规要求，相关的质量培训需要在代理商准入之前完成。

- L) Record Retention:** All records related to the Quality Annex must be retained by the Distributor/Dealer, with copies provided to Boston Scientific upon request. At termination of this agreement, Distributor/Dealer shall deliver all records (including traceability records in case of a field action) to Boston Scientific and shall direct future inquiries from customers to Boston Scientific.

Record retention requirements are as follows:

记录保存: 代理商/经销商必须留存与质量要求合同附件相关的全部记录，并在经请求时向波士顿科学提供副本。在本协议终止时，代理商/经销商应将全部记录（包括若有现场行动时的可追踪性记录）交给波士顿科学，并将以后来自客户的查询转向波士顿科学。

Type of Product 产品类型	Record Retention Timeframe 记录留存时间框架
Implantable Device 可植入式器械	Indefinitely 永久保存
Equipment 设备	Two years beyond dated removal from distribution (at least 5 years) or as otherwise indicated by Boston Scientific 自分销停止之日起两年后，但不得少于 5 年 或由波士顿科学另行指定，但不得少于 5 年
All Other Products 其他所有产品	At least Product lifetime/expiry + two years or as otherwise indicated by Boston Scientific (at least 5 years). 产品生命周期/保质期有效期+两年 或由波士顿科学另行指定，但不得少于 5 年

- M) Appointment of sub-distributors or sub-dealers or agents:** Distributor/Dealer that distributes Boston Scientific products through other entities (sub-distributors, sub-dealers) remains responsible for ensuring compliance with the Quality requirements in this Annex as well as ensuring that any complementary/supplementary Annexes are complied with until the product reaches the end customer.

下一级代理商/经销商/代理的任命: 代理商/经销商有责任确保，通过其他实体（下一级代理商/经销商/代理）分销波士顿科学产品时，应遵循和质量附件一样的质量要求，直到产品到达最终客户。

- N) Quality Assessments:** BSC reserves the right to perform on-site Quality assessments of the Distributor/Dealer facilities and processes prior to renewal or at any time during the contractual

relationship, to confirm Distributor/Dealer's adherence to the Quality requirements in this Annex.

质量审计: BSC 保留在代理商/经销商的现场进行质量审计的权利，审计内容包括设施和流程等。审计可以是在续约前或在合同关系有效期内的任何时间，以便确认代理商/经销商持续满足该附件的质量要求。

O) Other Requirements to Dealer/Distributor's Quality Management

关于经销商/代理商质量管理的其他要求

- 经销商/代理商经营第三类医疗器械，需持有有效的医疗器械经营许可证。经营范围应能覆盖波科给其授权给的产品范围。在合同期限内，如医疗器械经营许可证有任何变更，应及时通知波科进行备案。
 - 经销商/代理商经营第二类医疗器械，需持有有效的医疗器械备案凭证，或仍在有效期内的并且在《医疗器械经营监督管理办法》生效后未申请更换的医疗器械经营许可证。在合同期限内，申请或变更医疗器械备案凭证后，应及时通知给波科进行备案。
 - 经销商/代理商应建立起来符合法规要求的质量管理制度（包括进货查验制度，销售记录制度等）；应保存相关记录（或档案），并符合相关法规规定的追溯性要求。
 - 经营第三类医疗器械的经销商/代理商，应当具有符合医疗器械经营质量管理要求的计算机信息管理系统，保证经营的产品可追溯。计算机系统需经过验证和确认。
 - 医疗器械运输，储存过程需要符合产品说明书或标签标示要求。经销商/代理商委托其他机构运输医疗器械时，应当对承运方运输医疗器械的质量保障能力进行考核评估，明确运输过程中的质量责任，确保运输过程中的质量安全。
 - 经销商/代理商不得经营无合格证明文件，过期，失效，淘汰的医疗器械。
 - 依据商务合同，从有资质的经营企业/生产企业购进医疗器械。
 - 经销商/代理商应当销售产品给具有资质的经营企业或使用单位。
 - 经销商/代理商仓库中，过期、失效、淘汰的医疗器械要和合格产品隔离放置，以防止误发过期、失效、淘汰产品到用户。
- 经销商/代理商需要按时盘点仓库或者寄存在客户端的产品。在医疗器械产品将过效期前（建议提前 3 天），采取隔离措施，收回处理，以防止产品过期使用。

P) Product Receiving Check guidance

产品接收检查指导

步骤	措施
正常产品接收检查	
1	根据经销商/代理商自有管理体系要求，进行产品接受和检查
退回产品接收检查	
1	根据经销商/代理商自有管理体系要求，进行产品接受和检查
2	仓库操作员还应注意以下要点：
	2.1 对外观进行目视检查，产品应清洁无污染，封口标签是否完好。 注：如果本地添加的 CRM 外包装有打开痕迹或破损，则应进一步检查包装内产品是否完好正确。

Annex I – Dealer Quality Requirements

	<p>2.2 检查产品的标签标识包装是否完好。</p> <ul style="list-style-type: none"> • 对于 L-BSC 产品，标识包括中文标签，纸质中文说明书或光盘说明书； • 对于 CRM 产品，标识包括中文标签，Rohs 标签，光盘说明书，植入表，患者卡，入境货物检验检疫报告及医检所检验报告；并且确认两份检验报告上的产品序列号是否与实物一致。
	<p>2.3 检查说明书</p> <ul style="list-style-type: none"> • 对于纸质说明书及单产品光盘说明书，检查说明书产品名称是否与中文标签一致。
	<p>注 1：以下情况产品可以直接判定报废：</p> <ol style="list-style-type: none"> 1) 中文标签及说明书遗失，破损，内容/版本不正确； 2) 封口标签遗失或被破坏的（起搏器和除颤器除外）； 3) 无菌袋包装的产品在本地添加的塑料袋被破坏； 4) 产品损坏、受污染、受潮； 5) 中文标签上 4 个小标签被撕掉的，或在封袋中 4 张额外标签丢失）。 <p>注 2：产品包装完整性未受破坏，并且中文标签和中文说明书的信息清晰可读的前提下，其他不会影响二次销售的外观性瑕疵由经销商自行判断是否可以接受</p>
3	<p>仓库操作人员检查退货原因，如果是召回退货，<u>产品在检查后全部移到隔离区，然后根据波士顿科学指令进行退换货。</u></p>