產品服務與客退品處理程序制修訂記錄

文件版次	制修訂日期	發行日期	制修訂頁次	制修訂摘要	單位	制修訂者
1.0	2007/06/26			新發行		
1.1	2008/02/21		1-3	縮短處理程序及加速時效 2.0 範圍；3.1 & 3.5； 6.1.1 & 6.1.1.1~6.1.1.3 修訂 6.2.3 & 6.3.3 & 6.3.5 & 6.3.6 & 6.3.8		
1.2	2009/01/21		3	修訂 9.2 RMA 分析報告使用表單		
2.0	2010/03/05		1-5	3.0 制訂與權責單位變更為品保部 6.1.3 RMA No.西元碼變更為兩碼 6.3.4 & 6.3.5 & 6.3.6 & 6.3.7 & 6.3.8 & 6.3.9 6.4 處理時效規定修訂 10.1 客退品資訊流程圖 10.2 客退品貨品處理流程圖		
2.1	2010/10/29		1-3、6	3.4、3.6、3.7 因應組織擴大變動權責單位，文件格式修訂。		
2.2	2014/11/06		2-5	修正 6.3.1、6.3.9、8.2、9.6、9.7		
2.3	2016/04/13		1-4、6	3.6、3.7 因應組織調整變動權責單位，文件格式修訂。 10.2 客退品貨品處理流程圖。		
2.4	2017/08/26		1、2、3、5、6	修訂 因應組織調整，3.6、6.4、10.1、10.2 原倉管課修訂為資材部 修訂 3.1 分析報告變更為「分析與報告」 修訂 3.4 刪除「與寄送作業」 修訂 6.2.3、6.3.2、6.3.10		
2.5	2018/8/13		2、4	修訂 6.3.5 2 週內(14 天工作日內) 修訂 6.4.1 8D 流程各項作業處理時效規定		

				原則(For Schneider)		
2.6	2018/10/29		2 4 5 6 7	修訂 6.2.2 刪除財務相關流程。 修訂 8.6、8.7、8.8 修訂 9.10、9.11、9.12 修訂 10.1 流程圖內容 修訂 10.2 流程圖內容		
2.7	2019/11/15		1、2、6	修訂 6.4 作業項目內容 修訂 因應組織調整，3.5、6.2.3、6.3.2、10.1 原製程生技課修訂為生技課。		
3.0	2020/01/02		13	針對廠內 RMA 處理流程已擬定更細節的作業辦法作為後續客戶抱怨及 RMA 作業依循 客退品處理程序改名為產品服務與客退品處理程序		
3.1	2020/10/15	2020/11/03	5~13	修訂 補充內文中提到參考文件與使用表單的編號以利對應，修正文件名稱 修訂 6.12 將原有環境有害物質處理加回	品保部	郭姿意
3.2	2020/12/10	2021/03/12	1-16	1)導入 ISO13485 系統增加[醫療產品]敘述 2)修改 5.11.7 處理步驟，取代流程圖呈現方式 3)新增醫療產品退回或是召回處理方式 4)新增 6.13、6.14 參考文件 5)7.1 與 7.4 表單變更名稱	品保部	柯怡妏
3.3	2021/05/31	2021/06/10	3-28	新增英文，變更為中英文並行版本	品保部	虞閎立
3.4	2022/06/15	2022/06/29	5~10 20~23 32	新增維修流程內容	品保部	紀彥百
3.5	2022/12/13	2022/12/20	33	修訂 7.1、7.2、7.4、7.15 表單名稱	品保部	王信偉

3.6	2023/03/30	2023/04/13	17 34	修訂 5.3.5 異常單名稱 修訂 7.5 表單名稱	品保部	李士豪
3.7	2023/06/08	2023/06/29	1-37	1) 2.0 新增外購品 2) 5.0 新增流程圖 3) 5.1 B 階段描述變更 4) 5.1 C 階段描述變更 5)修訂 5.3.5 異常單名稱 6) 5.4 C 階段刪除成品與再製品處理 7) 5.4.4 刪除 8) 5.9.3 新增 RMA 分類 9) 5.10.3 修正改善未達預期由 B 項改為 C 階段進行真因調查 10) 5.11.1.1 新增文件保管期限 11)11.7 d&f. 將單位簡稱補上全名。 12) 6.15 新增參考文件 13) 修訂 7.5 表單名稱	品保部	李士豪

1.0 目的(Purpose):

對於時效內完成客戶反映產品品質議題及 RMA 退回品(含醫療產品)處理，通過發掘問題真因並實施針對性矯正及預防，使客戶的聲音及 RMA 退回品(含醫療產品)分析需求得以及時有效處理並預防產品(含醫療產品)品質問題再發生，以持續穩定產品品質，達成客戶滿意及持續改善。

To complete the processing of customer's feedback product quality issues and RMA returned products (including medical products) within the time limit, by finding the true cause of the problem and implementing targeted corrections and preventions, the voice of customers and the analysis needs of RMA returned products (including medical products) can be analyzed. Effectively handle and prevent the recurrence of product (including medical products) quality problems, so as to continuously stabilize product quality, achieve customer satisfaction and continuous improvement.

2.0 範圍(Scope):

凡客戶對 AMT 於產品開發送樣階段及量產階段之產品品質、外購品品質、交期及產品保固等方面所產生之回饋聲音、抱怨處理作業及 RMA 退回品(含醫療產品)作業均屬之。

All customers' feedback, complaints and RMA returned products (including medical products) operations generated by AMT during the product sampling stage and mass production stage of product quality, quality of outsourced products, delivery and product warranty.

3.0 定義(Definition):

3.1 客戶：接受AMT產品、客戶或代理商，包括外部客戶及AMT交貨客戶。

Customers: Accept AMT products, customers or agents, including external customers and AMT delivery product acceptors.

3.2 重大客訴：由AMT產品(含醫療產品)品質、產品含有害與關注物質、交期及產品保固等問題造成以下情形之客戶回饋意見或抱怨事件：

Serious customer complaints: customer feedback or complaints in the following situations caused by the quality of AMT products (including medical products), products containing harmful and concerned substances, delivery dates, and product warranty issues:

3.2.1 客戶停線或生產遭到延誤。
The customer stops production line or the production is delayed.

3.2.2 客戶產品(含醫療產品)因AMT責任導致被召回或退貨處理。
Customer products (including medical products) are recalled or returned due to responsibility belong to AMT.

3.2.3 因AMT責任導致客戶開出購回通知。
Due to AMT's responsibility, the customer issues a repurchase notice.

3.2.4 客戶將AMT從合格供應商除名或留單察看。
The customer removes the AMT from the qualified supplier or keeps an order for inspection.

3.2.5 因AMT責任致使樣品無法符合到客戶規格、應用及測試等需求，導致客戶無法承認。
Due to the responsibility of AMT, the samples could not meet the customer's specifications, applications and testing requirements, which led to the customer's failure to acknowledge.

3.3 客訴產品(含醫療產品)品質問題再發：
Customer complaints about product (including medical products) quality problems recurred

3.3.1 重覆發生因AMT責任導致相同或不同客戶針對同系列產品或不同批送樣樣品之相同缺點。
Repeated occurrence of the same shortcomings of the same or different customers for the same series of products or different batches of samples due to the responsibility of AMT.

3.4 產品保固(Product warranty)：
為對客戶承諾或承諾客戶要求之使用目標(或年限/次數等)或法令法規要求企業必須履行服務項目等，產品(含醫療產品)保固處理為當以上承諾項目未滿足時，需依承諾之要求賠償客戶損失，其處理方式有折讓、銷退、重工、退款、補貨、補償及換貨等。

To promise or promise the use target (or number of years/times, etc.) required by the customer or the law and regulations require that the company must perform the service items, the product (including medical products) warranty treatment is when the above commitment items are not met, the commitment must be followed Claiming compensation for the loss of customers, the processing methods include discount, sales return, heavy industry, refund, replenishment, compensation and exchange……, etc.

3.5 外部失敗成本(External failure cost)：

產品銷貨到客戶後，因產品品質(含醫療產品)、環境管理物質、交期及產品保固等問題而導致客戶抱怨、退貨、計劃外交付(含超額運費)及訂單減少等一系列損失所發生的全部費用。

After the product is shipped to the customer, due to product quality (including medical products), environmental management materials, delivery time and product warranty issues, customer complaints, returns, unplanned delivery (including excess freight), and order reductions are caused by a series of losses. All expenses incurred.

3.6 RMA退回品(含醫療產品)(Returned products (including medical products))：

3.6.1 指由於品質或導致客戶抱怨之問題，而被客戶要求退回工廠端之產品。

Refers to products that are required to be returned to the factory by customers due to quality or problems that have caused customers to complain.

3.6.2 指經確認客戶抱怨之產品問題屬於 AMT 責任，在考量節省雙方處理客訴品的人工成本和可避免的運輸成本前提下，經雙方同意列為換貨或銷折之產品。

Refers to the product problem that is confirmed to be complained by the customer that belongs to AMT's responsibility. Considering the labor cost and avoidable transportation cost for both parties to deal with the customer complaint, the product is listed as exchanged or sold-off product agreed upon by both parties.

3.7 客服維修品退回(Returned products for service repair)

產品銷貨到客戶後，指經確認產品品質問題非 AMT 責任時，AMT 接受客戶委託進行維修之產品。

Refers to products that AMT accepts to return by the customer for repair after it is confirmed that the products have quality issues that are not AMT responsibility after the products are sold.

4.0 權責(Ownership)：

4.1 行銷部(Sales and Marketing Division)：

4.1.1 與客戶建立良好關係。

Establish a good relationship with customers

4.1.2 蒐集客戶抱怨及 RMA 退回品(含醫療產品) 詳實資訊，並迅速通知品保及其他相關單位。

Collect detailed information on customer complaints and RMA returned products (including medical products), and promptly notify quality assurance and other related information department.

4.1.3 主導執行客戶端庫存調查及不良品處理，客戶要求時提出客戶補交貨需求。

Lead the execution of client inventory surveys and defective products processing, and put forward customer replenishment requirements when requested by customers.

4.1.4 追蹤客戶對改善之認可狀況及是否結案確認。

Follow customer's recognition of improvement and confirm whether the case is closed or not.

4.1.5 客服維修、客訴及 RMA 退回品(含醫療產品)客戶端相關不良處理費用評估，含重工/維修/退運/報廢/索賠等費用。

Customer complaints, RMA returned products (including medical products) and the products returned for service repair that client-related bad handling cost evaluation, including rework/repair/return/scrap/claims and other costs.

4.2 營運處最高主管(Chief Operating Executive)：

4.2.1 客戶抱怨與 RMA 案件確認及處理有效性與及時性之監督，指定改善團隊之領導人。

Confirmation of customer complaints and RMA cases and supervision of the

effectiveness and timeliness of processing, and designate the leader of the improvement team.

4.2.2 客戶抱怨及 RMA 案件處理對策之裁決與廠內改善結案之核示。

Customer complaints and rulings on RMA case handling countermeasures and verification of in-plant improvement and closure of the case.

4.3 品保部(Quality Assurance Department):

4.3.1 客戶抱怨、RMA 案件及客服維修受理、協調及回覆之內部作業窗口。

Internal operation for customer complaints, RMA case and the products returned for service repair acceptance coordination and response

4.3.2 召集相關單位組建處理團隊，分析客戶抱怨及 RMA 退回品(含醫療產品)資料，檢討原因及判定責任。

Convene relevant units to form a handling team to analyze customer complaints and RMA returned products (including medical products) data, review reasons and determine responsibilities.

4.3.3 協助責任單位檢討真因並於時效內彙總完成改善對策報告回覆行銷單位。

Assist the responsible unit to review the true cause and complete the improvement countermeasure report within the time limit. Reply to the marketing unit.

4.3.4 監督責任單位實施改善對策，確認改善對策執行效果及標準化狀況。

Supervise the implementation of improvement countermeasures by the responsible unit, confirm the implementation effect of the improvement countermeasures and the standardization status.

4.3.5 主導客訴或 RMA 退回品(含醫療產品)不良批及風險批之確認及處理。

Leading customer complaints or confirmation and handling of defective batches and risk batches of returned RMA products (including medical products).

4.3.6 會同相關單位定期檢討客訴及 RMA 退回品(含醫療產品)處理進度，跟催行銷單位確認客戶端認可及結案訊息。

Regularly review customer complaints and the processing progress of RMA returned products (including medical products) in conjunction with relevant units, and urge marketing units to confirm client approval and case closure messages.

4.3.7 定期階段性檢討客戶抱怨及 RMA 案件，分析客戶要求，監督內部持續改善。

Periodically review customer complaints and RMA cases, analyze customer requirements, and supervise continuous internal improvement.

4.4 研發部(R&D Department)：

4.4.1 負責設計、材料及樣品方面真因調查分析，提出改善對策報告並於時效內回覆品保單位。

Responsible for the investigation and analysis of the real cause of the design, materials and samples, propose improvement countermeasure reports and reply to the quality assurance unit within the time limit.

4.4.2 材料分析報告及材料驗證報告。

Material analysis report and material verification report.

4.4.3 設計方面、原材料及相關治具變更相關 ECN 作業。

ECN operations related to changes in design, raw materials and related fixtures.

4.4.4 內部宣導並貫徹執行矯正及預防再發對策。

Internally promote and implement corrective and prevent recurrence countermeasures.

4.5 生產部/工程部(Production Department/Engineering Department)：

4.5.1 負責客戶抱怨、客服維修及 RMA 退回品(含醫療產品)處理之技術支援及工程技術。

Responsible for technical support and engineering technology for handling customer complaints, RMA returned products (including medical products) and the products returned for service repair.

4.5.2 負責生產及工程段異常真因調查分析，提改善對策報告並於時效內回覆品保單位
Responsible for the investigation and analysis of the true cause of the abnormality in the production and engineering sections, propose improvement countermeasure reports and reply to the quality assurance unit within the time limit.

4.5.3 產品及生產製造過程變更時相關製程失效模式分析/PFMEA 之變更維護以及相關工程圖面與文件之工程變更通知/ECN 標準化。
Analysis of failure modes of related processes when products and manufacturing processes are changed / PFMEA change maintenance and engineering change notifications of related engineering drawings and documents / ECN standardization.

4.5.4 協助執行客戶抱怨、客服維修及 RMA 退回品(含醫療產品)處理過程中涉及之工程分析與檢測驗證作業。
Assist in the implementation of engineering analysis and testing and verification operations involved in the processing of customer complaints, RMA returned products (including medical products) and the products returned for service repair.

4.5.5 生產單位提供相關生產紀錄。
The production function department shall provide relevant production records.

4.6 資材部生管課 (Production management section of the Materials Department)：

4.6.1 主導因廠內產品(含醫療產品)生產交期、製令排程、運輸過程出問題以及自然災害等原因導致的交期延遲等相關的客訴。
Leading customer complaints related to delays in delivery due to in-plant products (including medical products) production and delivery, manufacturing order scheduling, transportation problems, and natural disasters.

4.6.2 確認廠內庫存及在製品(或風險批)數量。
Confirm the inventory in the factory and the quantity of work in process (or risk batch).

4.6.3 會同品保單位處理客戶抱怨、客服維修及 RMA 退回品(含醫療產品) (或風險批)及安排不良品重工、維修或報廢。

Cooperate with the quality assurance unit to handle customer complaints, RMA returned products (including medical products) (or risk batches) and the products returned for service repair and arrange the defective product to rework, repair or scrap.

4.6.4 負責客戶抱怨、客服維修或 RMA 不良品(含醫療產品) (或風險批)之補(換)貨計劃擬定與安排生產補貨。

Responsible for the formulation of replenishment (replacement) plans for customer complaints, RMA returned products (including medical products) (or risk batches) and the products returned for service repair and arranging production replenishment.

4.6.5 客訴、客服維修及 RMA 退回品(含醫療產品)廠內相關處理費用評估，含重工/維修/報廢等費用。

Evaluation of processing costs for customer complaints, RMA returned products (including medical products) (or risk batches) and the products returned for service repair, including rework/repair/scrap and other costs.

4.7 財務部(Finance Department)：

4.7.1 必要時協助業務單位提供不良品(風險批)之失敗成本數據資料，配合執行索賠相關作業。

When necessary, assist business units to provide failure cost data of defective products (risk batches), and cooperate with the execution of claims related operations.

4.7.4 定期彙總提供各單位外部失敗成本供各單位及高階管理層作為持續改善參考。

Regularly summarize and provide external failure costs of each unit for each unit and senior management as a reference for continuous improvement.

4.8 資材部採購課(Logistic Department / Procurement Section)：

4.8.1 協助處理客戶抱怨、客服維修或 RMA 退回品(含醫療產品)中涉及供應商端之責任確認，要求供應商就客戶抱怨及 RMA 退回品(含醫療產品)異常進行改善並追蹤成效。

Assist in handling customer complaints, RMA returned products (including medical products), or the products returned for service repair that involving the supplier's responsibility confirmation, requiring suppliers to improve customer complaints and RMA returned products (including medical products) abnormalities and track the results.

4.8.2 協助處理由供應商交期延遲導致之客戶抱怨。

Assist in handling customer complaints caused by supplier delivery delays.

4.9 改善團隊領導人(Improve team leader)：

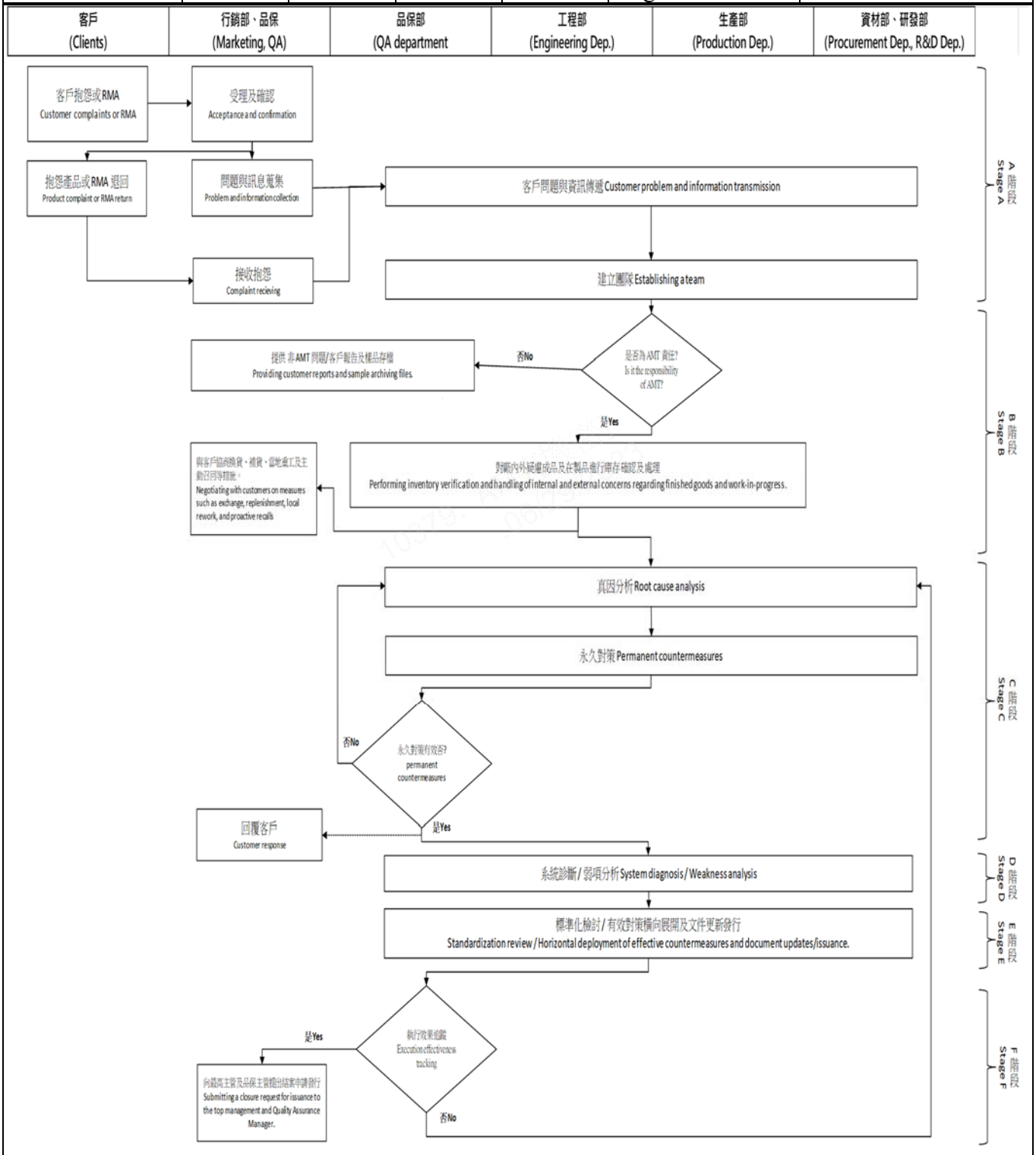
4.9.1 提供改善團隊成員客訴或 RMA 退回品(含醫療產品)改善過程中所需資源。

Provide the resources needed to improve the customer complaints of team members or RMA returned products (including medical products) in the improvement process.

4.9.2 統籌安排相關單位作業，找出問題真因，提出改善對策，並確保改善對策有效。

Coordinate the work of relevant units, find out the real cause of the problem, propose improvement measures, and ensure the effective.

5.0 執行步驟(Execution Steps)：



5.1重大客訴及RMA退回品(醫療產品)處理程序包含以下階段：

The processing procedures for major customer complaints and RMA returned products (medical products) include the following stages:

A 階段：客戶告知、回覆客戶已獲悉客訴或RMA退回品(含醫療產品)通知及現狀，抱怨產品或RMA退回品(含醫療產品)退回工廠。

Stage A: The customer informs and responds. The customer has been informed of the customer complaint or the notification and status of the RMA returned product (including medical products), and the complaint product or the RMA returned product (including medical products) is returned to the factory.

B 階段：問題判定，改善團隊建立，廠內疑慮成品(含醫療產品)及在製品(含醫療產品)處理。

Stage B: Problem determination, team building improvement, and handling of internal concerns regarding finished goods (including medical products) and work-in-progress (including medical products).

C 階段：確定真因及再發預防對策。

Stage C: Determine the true cause and preventive countermeasures for recurrence.

D 階段：預防對策系統診斷及驗證分析。

Stage D: Diagnosis and verification analysis of preventive countermeasures system.

E 階段：標準化。

Stage E: Standardization.

F 階段：執行追蹤。

Stage F: Execution trace and confirmation.

5.2 A 階段：客戶告知、回覆客戶已獲悉客訴或RMA退回品(含醫療產品)通知及現狀，抱怨產品或有RMA(含醫療產品)退回工廠，處理時效以24小時內完成為宜。

Stage A: The customer has been notified of customer complaints or RMA returned products (including medical products) and the status, and complaints about products or RMA (including medical products) are returned to the factory. The processing time limit should be completed within 24 hours.

5.2.1 業務或行銷單位接獲任何客戶告知意見、抱怨或RMA退回品(含醫療產品)訊息時，行銷單位應立即向客戶端確認並調查客戶抱怨或RMA退回品(含醫療產品)之完整資訊(包括客戶名稱、客戶工廠所在地、抱怨或RMA退回品(含醫療產品) 料號/系列、不良率/數、不良製令、不良情形、客戶應用製程、使用或測試方式、產品保固失效情形及競爭對手產品在客戶段使用狀況等) 以文字、圖片或影像等形式填入〔RMA申請單〕（7.4）中，並以公司電子郵件等方式通知負責該產品之品保單位，不得以口頭通知或蓄意隱瞞或傳遞不實之訊息。如其它單位先獲得客戶抱怨訊息，應及時通知業務及行銷單位，行銷單位與客戶確認並將相關資訊填入至表單中。

When the business or marketing department member receives any customer's comments, complaints, or information about RMA returned products (including medical products), the marketing unit should immediately confirm to the client and investigate the customer’s complaints or the integrity of the RMA returned products (including medical products) Information (including the name of the customer, the location of the customer's factory, complaints or RMA returned products (including medical products), part number/series, defective rate/number, bad manufacturing order, bad situation, customer application process, use or testing method, product warranty invalidation situation And competitors’ products in the customer segment, etc.) Fill in the "Customer Feedback and RMA Returned Product (Medical Products) Notification Form" (7.4) in the form of text, pictures or images, and notify the responsible person by company email etc. The quality assurance unit of the product shall not verbally notify or deliberately conceal or transmit false information. If other units receive customer complaints first, they should promptly notify the business and marketing unit, and the marketing unit will confirm with the customer and fill in the relevant information in the form.

5.2.2 客戶抱怨或RMA退回品(含醫療產品)資訊如不完整時，品保單位應視需要要求行銷單位協助調查或提供更進一步資訊，必要時應親至客戶端進行了解，不得藉故延遲

時效或推諉不進行抱怨處理。如為非品質異常導致交貨過程控制問題(廠內交期確認、製令安排、運輸過程問題導致的交期延遲客訴、廠外運輸過程中混料及損壞等)，品保或物管單位應即時通知生管單位確認。

If the customer complaints or the information of the RMA returned product (including medical products) is incomplete, the quality assurance unit should request the marketing department to assist in the investigation or provide further information as necessary, and should go to the client for understanding if necessary, and no delay should be allowed. No complaints will be dealt with within the time limit or prevarication. If it is a non-quality abnormality that causes control problems in the delivery process (factory delivery confirmation, manufacturing order arrangements, customer complaints for delays in delivery due to problems in the transportation process, mixing and damage during off-site transportation, etc.), the quality assurance or property management unit The production management unit should be notified immediately for confirmation.

5.2.3 此階段資料輸入完整後，由行銷業務單位主管確認後正式立案處理。

After the data at this stage is completed, it will be formally filed for processing after confirmation by the head of the marketing business department.

5.2.4 行銷單位應調查並了解客戶對客訴及RMA退回品(含醫療產品)處理特殊要求(如處理時效、改善報告格式、提交資料內容、客戶對物料處理要求等)，並將其特殊要求填入至〔RMA申請單〕（7.4）。

Marketing units should investigate and understand the special requirements of customers for handling customer complaints and RMA returned products (including medical products) (such as processing timeliness, improvement of report format, content of submitted materials, customer requirements for material handling, etc.) It is required to fill in the "Customer Feedback and RMA Returned Product (Medical Product) Notice" (7.4).

5.2.5 行銷單位與客戶協調好以接收客戶抱怨產品或RMA退回品(含醫療產品)退回工廠

The marketing department coordinated with customers to receive customer complaints or RMA returned products (including medical products) returned to the factory.

5.3 B 階段：問題判定，改善團隊建立，採行暫時對策，處理時效以48小時內完成為宜。
Stage B: Problem determination, improvement of team establishment, temporary countermeasures, and the treatment timeliness should be completed within 48 hours.

5.3.1 品保單位接獲客戶抱怨或RMA退回品(含醫療產品)完整資訊後，應主導會同相關單位(包括業務、生產、工程、採購、生管及研發等相關單位)組成改善團隊，針對客訴或RMA退回品(含醫療產品)信息(被退回之不良樣品/產品、相關數據、影像資料與交期等)進行失效分析檢討，並由品保單位會同處理團隊針對不良批及影響程度研判提出遏止計劃(即臨時對策)並執行之，同時查找客訴或RMA退回品(含醫療產品)產生的真正原因加以改善預防。
備註：改善團隊之領導人原則上由副總級主管擔任。
After receiving customer complaints or complete information on RMA returned products (including medical products), the quality assurance unit shall lead to form an improvement team with related units (including business, production, engineering, procurement, production management, research and development, etc.) to respond to customer complaints or RMA returned product (including medical products) information (returned defective samples/products, related data, image data, and delivery date, etc.) for failure analysis and review, and the quality assurance unit and the processing team will research and judge the bad batch and the degree of impact Containment plans (ie, temporary countermeasures) and implement them, and at the same time find out the real causes of customer complaints or RMA returned products (including medical products) to improve and prevent.
Remarks: Generally speaking, the leader of the improvement team is assumed by the deputy general manager.

5.3.2 行銷單位應針對此產品在客戶端之不良模式及客戶要求提出說明。
The marketing department should provide explanations for the bad patterns of this product on the client side and customer requirements.

5.3.3 針對產品品質不良，由研發、工程、生產、品保及採購等單位針對不良模式從設計及製造等因素提出可能導致不良模式產生之原因；對於品質異常導致之交期延遲，由品保、生管、物流及銷售等單位從交期確認、運輸及倉儲等因素提出可能導致問

題模式產生之原因；對非產品品質異常導致交貨過程控制問題 (廠內交期確認、製令安排、運輸過程出問題以及自然災害等原因導致的交期延遲客訴、廠外運輸過程中混料及損壞等)由生管單位召集運籌、物流與業管等單位主導提出可能導致問題模式產生之原因，完成 B～C階段處理。

In response to poor product quality, the R&D, engineering, production, quality assurance, and procurement units will propose the reasons that may lead to the bad mode from the design and manufacturing factors; for the delayed delivery due to abnormal quality, the product The units of insurance, production management, logistics and sales put forward the reasons that may lead to the problem mode from factors such as delivery confirmation, transportation and warehousing; for non-product quality abnormalities that lead to delivery process control problems (factory delivery confirmation, manufacturing order arrangement , Transportation problems and natural disasters caused by delays in delivery, customer complaints, mixing and damage during off-site transportation, etc.) The production management section convenes operations research, logistics and industry management and other units to propose the reasons that may lead to the problem mode, Complete the B ~ C stage processing.

5.3.4 品保單位應會同生產相關單位依據《產品鑑別與追溯程序》（6.10），對客戶回饋意見、抱怨或RMA退回品(含醫療產品)產品相關製程管制資料(4M1E管理、5問法(5-Why)及製程異常處理記錄等)及相關品質履歷(首件、巡檢、入庫、出貨品質檢驗記錄及不良樣品/留樣品品質及特採記錄等)進行確認，以找出初步原因，確定受影響範圍，鎖定不良風險批號/次，並制定臨時作業對策。

The quality assurance unit shall, in conjunction with the relevant production units, provide feedback, complaints, or RMA returned products (including medical products) to customers in accordance with [Product Identification and Traceability Procedures] (6.10), product-related process control data (4M1E management, 5 questions) (5-Why) and abnormal process records, etc.) and related quality history (first article, patrol, warehousing, outgoing quality inspection records, bad samples/retained sample quality and special procurement records, etc.) for confirmation to find out the preliminary Reason, determine the affected area, lock the bad risk batch number/time, and formulate temporary operation countermeasures.

5.3.5 若為供應商交貨品質問題，則由品保單位會同相關單位與供應商進行檢討確認，鎖定不良批，必要時開立〔進料品質異常通知單〕（7.5）要求提出書面改善行動報告以預防再發。

If it is a quality problem of the supplier's delivery, the quality assurance unit will review and confirm with the relevant unit and the supplier, lock the defective batch, and if necessary, issue an "Incoming Material Quality Abnormal Form" (7.5) to request a written improvement action report. Prevent recurrence.

5.3.6 客戶抱怨及RMA退回品(醫療產品)相關不良品(或風險批)之追蹤確認、處理與主動召回

Tracking confirmation, handling and proactive handling of customer complaints and RMA returned products (medical products) related defective products (or risk batches) Recall.

A. 廠內於客戶抱怨或RMA退回品(含醫療產品)發生後需對不良品(或風險批) 進行追蹤確認時，品保單位應會同生管及責任單位確認廠內庫存及已出貨之在途品及客戶端(含已出貨之其他客戶，下同)庫存數量及疑慮範圍，並立即通知各相關對應業務人員及時對不良品(或風險批)進行全面品質確認。

When the factory needs to track and confirm defective products (or risk batches) after a customer complaint or RMA returned products (including medical products) occur, the quality assurance unit should work with the production management and responsible unit to confirm the inventory and shipments in the factory In-transit products and clients (including other customers who have already shipped, the same below) inventory quantity and doubt range, and immediately notify the relevant corresponding business personnel to conduct a comprehensive quality confirmation of defective products (or risk batches) in a timely manner.

B. 廠內的不良品(或風險批)應依據《不合格品管制程序》（6.11）進行處理，已交貨給客戶的不良品 (或風險批) 則由行銷向客戶委婉說明已交貨不良品之異常情形，並協商具體補救措施以消除該異常對客戶所造成的不利影響，以期達成客戶滿意，並將公司損失降至最低。

Defective products (or risky batches) in the factory should be handled in accordance with [Non-conforming product control procedures] (6.11), and for defective products (or risky batches) that have been delivered to customers, marketing will euphemistically explain to customers that they have been delivered. The abnormal situation of defective products, and negotiate specific remedial measures to eliminate the adverse impact of the abnormality on the customer, in order to achieve customer satisfaction and minimize the company's losses.

C. 補救措施通常包括折讓、銷退、換貨、當地重工、重新交貨及補貨等。無法當地重工處理的不良品應由廠內主動召回。當不良品已對客戶製程造成損失(包括已造成客戶產品品質異常、客戶斷線及客戶遭受使用者抱怨等情形)而導致客戶索賠時，相關賠償作業也應與補救措施一併執行。

Remedial measures usually include discounts, sales returns, exchanges, local heavy industry, re-delivery and replenishment, etc. Defective products that cannot be handled by the local heavy industry should be recalled by the factory. When the defective product has caused losses to the customer's manufacturing process (including the customer's product quality abnormality, the customer's disconnection, and the customer's complaints from the customer) resulting in a customer claim, the relevant compensation work should also be implemented together with the remedial measures.

5.4 C階段：確定真因及再發預防對策，處理時效以48小時內完成為宜。

Stage C: Determine the root cause and re-issue preventive countermeasures. The treatment time should be completed within 48 hours.

5.4.1 改善團隊之領導人應統籌生產、工程與品保、資材相關單位，結合客戶應用需求，確認客戶規格、廠內規格，對客戶製程、廠內製程進行分析驗證，通過模擬驗證及不良再現確保找出問題真因預防不良再次發生。

The leader of the improvement team should coordinate production, engineering, quality assurance, and materials related units, combined with customer application requirements, confirm customer specifications, in-plant specifications, analyze and verify customer processes and in-plant processes, and ensure that they are found through simulation

verification and defect reproduction. The problem happened again because of poor prevention.

5.4.2 各責任單位結合真因分析結果提出永久改善對策給品保單位(當影響因素不止一項時，應依各因素影響度及執行先後順序層別改善對策之執行步驟)，品保單位綜合各責任單位改善對策後，彙整管理追蹤並提出正式〔矯正行動報告〕（7.3）(8D報告或依客戶指定格式之改善報告)，經品保最高權責主管核示後，交行銷單位回覆客戶。不同責任單位所提改善成長對策有衝突或無法銜接時，應由改善團隊之領導人主導協調以確保改善成長對策能有效執行。若無特別需求，客戶之客訴及RMA原因分析及永久改善對策則以〔客退品分析報告〕（7.2）回覆。

Each responsible unit combines the results of the true cause analysis to propose permanent improvement measures to the quality assurance unit (when there are more than one influencing factors, the implementation steps of the improvement measures should be classified according to the influence of each factor and the order of execution), and the quality assurance unit integrates all responsibilities After the unit improves the countermeasures, the management, tracking, and a formal "corrective action report" (7.3) (8D report or improvement report in the format specified by the customer) are collected and managed. After verification by the highest quality assurance supervisor, the sales unit will reply to the customer. When the improvement and growth strategies proposed by different responsible units conflict or cannot be connected, the leader of the improvement team shall lead and coordinate to ensure that the improvement and growth strategies can be effectively implemented. If there is no special demand, customer complaints and RMA cause analysis and permanent improvement measures will be responded to with "RMA Customer Returned Product Analysis Report" (7.2).

5.4.3 C 階段相關資料應由品保相關責任單位填入〔矯正行動報告〕（7.3）中，品保單位確認其正確性及完整性，當發現C階段資料不正確/不完整時，須退件至責任單位並要求持續改善。

The relevant information of stage C should be filled in by the responsible unit of quality assurance in the "Corrective Action Report" (7.3), and the quality assurance unit shall confirm its correctness and completeness. When the information of stage C is found to be incorrect/incomplete, it shall be returned to Responsible unit and require continuous

improvement

5.5 D 階段：品質系統診斷及分析

Stage D: Quality system diagnosis and analysis.

5.5.1 品保單位應會同改善團隊成員依客戶回饋意見與RMA退回品(含醫療產品)真因分析結果，回饋至產品開發相關階段進行分析，並將分析結果填寫於〔RMA退回分析單〕（7.1）或〔OFM RMA退回分析維修單〕（7.14）進行系統診斷及分析。

The quality assurance unit should work with the improvement team members to analyze the true cause of the RMA returned products (including medical products) based on customer feedback and feedback to the relevant stage of product development for analysis, and fill in the analysis results in the analysis of RMA returned products (medical products) Single (7.1) for system diagnosis and analysis.

5.5.2 若為非品質異常導致交貨過程控制問題(如廠內交期確認、製令安排、運輸過程出問題以及自然災害等原因導致的交期延遲客訴、廠外運輸過程中混料及損壞等)，由生管單位填寫〔RMA退回分析單〕（7.1）或〔OFM RMA退回分析維修單〕（7.14）進行品質系統診斷及不良分析。

If it is a non-quality abnormality that leads to control problems in the delivery process (such as delivery confirmation in the factory, manufacturing order arrangements, problems in the transportation process, and natural disasters, customer complaints for delays in delivery, mixing and damage during off-site transportation, etc.) , Written by the production management unit (customer feedback and RMA returned products (including medical products) analysis sheet) (7.1) or "OFM RMA Returned Products(including Medical Products) Analysis/Repair Sheet" (7.14) for quality system diagnosis and failure analysis.

5.6 E階段：標準化

Stage E: Standardization

5.6.1 各責任單位(生產、品保、研發及生管等)應依改善成長對策，完成標準化文件檢討，並視需求將改善成長對策納入相關管制文件中予以標準化。對於驗證確認有效之改

善對策，需橫向展開至其它相關產品生產製作過程。

All responsible units (production, quality assurance, R&D, production management, etc.) shall complete the review of standardized documents in accordance with the improvement measures for growth, and incorporate the improvement measures into the relevant control documents for standardization as required. For the verification and confirmation of effective improvement measures, it needs to be expanded horizontally to the production process of other related products.

5.6.2 涉及產品及生產製作過程變更之改善對策應返回製程失效模式效應分析/PFMEA文件中進行分析，必要時應對製程失效模式效應分析/PFMEA及相關工程/品質管制文件(如工程圖面、產品品質管制計劃、作業規範、檢驗規範、產品規格及包裝規範等)進行修訂，作為品質系統持續改善之參考依據，以利經驗之傳承，適用此改善經驗應展開至同系列或類似產品及生產製造程序。產品與生產製造過程變更應依據《設計變更管制程序》（6.12）之相關規定辦理ECR/ECN變更、驗證、會簽及發行作業，並依規定執行通知客戶並獲得客戶同意。

Improvement measures involving changes in products and production processes should be returned to the process failure mode effect analysis/PFMEA document for analysis. If necessary, the process failure mode effect analysis/PFMEA and related engineering/quality control documents (such as engineering drawings, product quality control) Plans, work specifications, inspection specifications, product specifications, packaging specifications, etc.) are revised as a reference for continuous improvement of the quality system to facilitate the inheritance of experience. The application of this improvement experience should be expanded to the same series or similar products and manufacturing procedures. Product and manufacturing process changes shall be handled in accordance with the relevant regulations of [Design Change Control Procedure] (6.12) for ECR/ECN changes, verification, countersignature and issuance, and the implementation of the regulations shall notify the customer and obtain the customer's consent. .

5.6.3.產品及過程變更應重新檢討相關作業依據之規定執行。

Product and process changes shall be re-reviewed and implemented according to the

relevant regulations.

5.6.4 E階段相關資料應由相關責任單位填入〔RMA退回分析單〕（7.1）或〔OFM RMA退回分析維修單〕（7.14）中，品保單位追蹤確認其正確性及完整性。

The relevant information of stage E should be filled in by the relevant responsible unit in the "Customer Feedback and RMA Returned Products (including Medical Products) Analysis Sheet" (7.1) or "OFM RMA Returned Products(including Medical Products) Analysis/Repair Sheet" (7.14), and the quality assurance unit will track and confirm its correctness and completeness.

5.7 F階段：執行追蹤

Stage F: Execution trace and follow

5.7.1 品保管制單位應追蹤確認各責任單位改善成長對策之執行狀況及改善效果，經追蹤確認原有之不良原因已消除，且改善對策已於PFMEA/SOP/SIP等相關文件中標準化並於發行時，品保單位應將廠內追蹤狀況及相關資料填入〔RMA退回分析單〕（7.1）或〔OFM RMA退回分析維修單〕（7.14）中，並提出廠內段結案申請。(若為非品質異常導致交貨過程控制問題，由生管單位追蹤確認各責任單位改善對策之執行狀況及改善效果，生管主管確認廠內改善對策已完成且達到改善效果後以書面形式通知品保單位。)

The quality assurance control unit shall track and confirm the implementation status and improvement effect of each responsible unit's improvement measures for growth. The tracking confirms that the original bad causes have been eliminated, and the improvement measures have been standardized and standardized in relevant documents such as PFMEA/SOP/SIP. At the time of issuance, the quality assurance unit should fill in the tracking status and relevant information in the factory into the "Customer Feedback and RMA Returned Products (Including Medical Products) Analysis Sheet" (7.1) or "OFM RMA Returned Products(including Medical Products) Analysis/Repair Sheet" (7.14), and submit an application for closing the case in the factory. (If it is a non-quality abnormality that caused the delivery process control problem, the production management unit will track and confirm the implementation status and improvement effect of each responsible unit's improvement countermeasures, and the

production management supervisor will notify in writing after confirming that the in-plant improvement countermeasures have been completed and the improvement results have been achieved.)

5.7.2 行銷單位接到廠內結案申請時，應將F階段追蹤記錄轉客戶確認(書面文件或E-mail)，追蹤客戶端對永久改善對策、改善樣品/產品以及相關文件之認可狀況，確認無誤後將客戶結案資訊通知結案者。

When the marketing unit receives an application for closing a case in the factory, it shall forward the Phase F tracking record to the customer for confirmation (written document or E-mail) to track the client's approval status for permanent improvement measures, improved samples/products and related documents. After the confirmation is correct, the client will be notified of the case closure information.

5.7.3 行銷業務單位及品保最高權責主管確認客訴或RMA退回品(醫療產品)相關資料無誤後簽認，行銷業務主管結案復審無誤後簽認。行銷單位權責主管對客戶段追蹤訊息進行確認簽署，經行銷業務主管確認後此客戶抱怨或RMA案件結案。

The marketing business unit and the top quality assurance supervisor confirm that the customer complaint or RMA returned product (medical product) related materials are correct, and then sign, and the marketing business supervisor sign after the case is correct after the review. The responsible manager of the marketing unit confirms and signs the tracking information of the customer segment, and the customer complaints or the RMA case is closed after the marketing business manager confirms it.

5.7.4 若行銷單位於廠內改善完成半年內追蹤不到客戶給予之正式認可或承認郵件等結案通知，且此客戶抱怨在此期間內未有再發(或該產品自此不再生產或交貨)，由行銷單位於〔RMA退回分析單〕（7.1）或〔OFM RMA退回分析維修單〕（7.14）說明追蹤現狀，並提出結案申請。

If the marketing unit fails to track the closing notice given by the customer within half a year after the completion of the improvement in the factory, and the customer complains that it has not been reissued within this period (or the product is no longer produced or delivered) The marketing unit will explain the tracking status in "Customer feedback and RMA returned products (including medical products) analysis sheet" (7.1) or "OFM

RMA Returned Products(including Medical Products) Analysis/Repair Sheet" (7.14), and submit an application for closing the case.

5.8 客戶抱怨爭議處理

The customer complains about the dispute settlement.

5.8.1 各責任單位間就客戶抱怨或RMA退回品(含醫療產品)處理如有爭議時，由品保單位協調處理，必要時提出解決方案呈權責主管核定，爭議雙方依核定之解決方案執行。

If there is a dispute between the responsible units regarding customer complaints or RMA returned products (including medical products), the quality assurance unit shall coordinate and deal with it, and if necessary, propose a solution to the responsible supervisor for approval, and the parties to the dispute shall follow the approved solution carried out.

5.9 客退品之申請（Application for customer return）

5.9.1 確認RMA退回成立時，告知品保負責窗口提供RMA 編號No，負責業務將最新版〔RMA申請單〕（7.4）給客戶填寫相關資訊後，請客戶將〔RMA申請單〕（7.4）及不良品一併寄回AMT

When confirming the establishment of the RMA return, inform the quality assurance window to provide the RMA number No. The responsible business will provide the latest version of the customer feedback (customer feedback and RMA returned product (including medical products) notice) (7.4) after filling in the relevant information to the customer, Customers are requested to send "Customer feedback and RMA returned product (including medical products) notification form" (7.4) and defective products to AMT.

5.9.2 若客戶未先告知，先寄回不良品，客退品入廠後，品保負責窗口接收時，應先查看退回品狀況，並編定RMA No，將資訊通知業務。

If the customer does not inform first, the defective product will be returned first. After the returned product is received in the factory, the quality assurance window should first check the status of the returned product, edit the RMA No, and notify the business of the information.

5.9.3 RMA分類為：RMA(T/P客訴)、ORRMA(外購品客訴)、OFRMA(光貼產品客訴)三種，

RMA編碼原則如下。

RMA classification consists of three types: RMA (T/P complaint), ORRMA (outsourced product complaint), and OFRMA (optical bonding product complaint). The coding principles for RMA are as follows.

RMA 編號No，編碼說明:RMA21 001

21:西元年最後兩碼，例如:2021年

001:流水號

RMA number No, code description: RMA21 001

21: The last two digits of the first year, for example: 2021

001: serial number

5.9.4 RMA 編號No，由品保人員予以管制追查與列出清單，RMA 編號No為日後客戶回饋意見與〔RMA退回分析單〕（7.1）號碼與查詢使用依據。

RMA No., which is controlled and tracked by quality assurance personnel and listed in the list. RMA No. is for future (customer feedback and RMA returned product (including medical products) analysis sheet) (7.1) number and the basis for inquiries.

5.10 處理時效（Treatment time efficiency）

5.10.1 當客戶有明確要求處理時效時，由行銷單位將其要求填入〔RMA申請單〕(7.4)，品保單位應會同各責任單位嚴格按照客戶要求於時效內完成案件處理。當客戶無具體時效要求時，客戶抱怨處理時效原則上應依以下要求執行：

When the customer has a clear request for the processing time limit, the marketing department will fill in the request into the "Customer Feedback and RMA Returned Product (Medical Product) Notice" (7.4). The quality assurance unit shall work with each responsible unit in strict accordance with the customer It is required to complete the case processing within the time limit. When the customer has no specific time limit requirements, the time limit for handling customer complaints shall in principle be

implemented in accordance with the following requirements:

A 階段 A stage	B 階段 B stage (Accumulation)	C 階段 C stage (Acc.)	D 階段 D stage (Acc.)	E 階段 E stage (Acc.)	F 階段 F stage (Accumulation)
24 hrs.	72 hrs.	120hrs	144hrs	168 hrs.	180 hrs.

註：當客戶抱怨或 RMA 處理作業中涉及產品/過程變更或需發包設備/模治具時，上述 C 階段處理完成週期為 720 hrs. (累加)。

Note: When customers complain or RMA processing involves product/process changes or equipment/mold fixtures need to be contracted, the above-mentioned stage C processing completion cycle is 720 hrs. (Accumulation).

5.10.2 當客戶抱怨或RMA退回品(含醫療產品)處理需要較長時間(超過以上作業時效規定)的追蹤或驗證週期以致無法於上述C階段作業時效內完成〔客退品分析報告〕（7.2）或〔矯正行動報告〕（7.3）時，應由品保單位先行檢討提出需分析驗證的問題點及預定作業時間，以初步〔客退品分析報告〕（7.2）或〔矯正行動報告〕（7.3）或其他客戶認可之書面方式(如郵件等)通過行銷單位與客戶說明，並確定〔客退品分析報告〕（7.2）或〔矯正行動報告〕（7.3）正式提交日期，以避免因延誤回饋時間造成客戶不滿意。當此情形發生時，廠內各相關責任單位應嚴格按照與客戶商定的時效完成改善。品保單位應跟催相關責任單位，並視需要通知其主管督促案件處理時效。

When a customer complaint or the processing of RMA returned products (including medical products) requires a long tracking or verification cycle (exceeding the above operating statutes), it is impossible to complete the "Customer Returned Product Analysis Report" within the above-mentioned stage C operating statute. (7.2) or "Corrective Action Report" (7.3), the quality assurance unit should first review and put forward the problem points that need analysis and verification and the scheduled operation time, to make a preliminary "Customer Returned Product Analysis Report" (7.2) or "Corrective Action Report". (7.3) Or other written methods approved by the customer (e.g. mail, etc.) through the marketing unit and the customer, and determine the "Customer Returned Product Analysis Report" (7.2) or "Corrective Action Report" (7.3) the official

submission date to avoid Delayed feedback time causes customer dissatisfaction. When this happens, all relevant responsible units in the factory shall complete the improvement in strict accordance with the time limit agreed with the customer. The quality assurance unit shall follow up the relevant responsible unit and notify its supervisor as necessary to supervise the handling of the case.

5.10.3 當廠內追蹤發現改善未達預期效果，品保單位應會同處理團隊回到C階段進行真因分析進行調查改善，直至客戶滿意為止。

When the tracking in the factory finds that the improvement has not achieved the expected effect, the QA team, in collaboration with the relative departments to conduct root cause analysis and investigation and the improvement until the customer's satisfaction is achieved.

5.11 資料統計及管理 (Data statistics and management) :

5.11.1 客戶抱怨及RMA之相關資料(抱怨資料、處理經過、退回樣品/產品分析驗證抱怨、責任單位對策擬定與執行、改善成效追蹤、所涉及之相關標準化作業等)應由行銷、品保及改善責任單位分別歸檔管理。

Customer complaints and RMA related data (complaints, processing history, returned samples/product analysis and verification complaints, responsible unit countermeasures formulation and implementation, improvement performance tracking, related standardized operations involved, etc.) shall be covered by marketing and quality assurance And improve the responsible unit to archive management separately.

5.11.1.1 檔案保存期限參照〔品質(含醫療產品)、環境、能源與職業安全衛生記錄管理程序〕(6.15)。

The file retention period refers to the Quality (including medical products), Environmental, Energy, and Occupational Health and Safety Records Management Procedures.(6.15)

5.11.2 客戶抱怨及RMA處理所涉及之工程圖面/文件變更(ECN)應依據《設計變更管制程序》（6.12）之相關規定辦理正式發行。

The engineering drawings/document changes (ECN) involved in customer complaints and RMA processing shall be officially issued in accordance with the relevant

provisions of [Design Change Control Procedures] (6.12).

5.11.3 數據統計(Data Statistics)

5.11.3.1 一般要求(General requirements)

品保單位應就客戶抱怨及RMA建立適當管制指標，包括客戶抱怨 / RMA不良PPM / 件數、處理時效、結案率、外部失敗成本、造成客戶生產中斷時間等，依月度、季度及年度定期檢討，分析了解實際作業中存在的改善需求，在此基礎上維護修訂內部管制指標要求，監督各單位持續改善。

The quality assurance unit shall establish appropriate control indicators for customer complaints and RMA, including customer complaints/ RMA worse ppm/number of pieces, processing timeliness, closing rate, external failure costs, time for customer production interruptions, etc., and review them on a monthly, quarterly and annual basis. Analyze and understand the improvement needs in actual operations, maintain and revise the internal control index requirements on this basis, and supervise the continuous improvement of all units.

5.11.3.2 客戶特殊要求-數據統計報告行銷單位需依客戶要求準備以下數據統計報告。

Customer special requirements-data statistics report Marketing units need to prepare the following data statistics report according to customer requirements.

5.11.4 品保/財務單位應蒐集每次客戶抱怨及RMA所產生之外部失敗成本，並依各行銷業務進行階段性(月度/季度/年度)統計，以提供給公司高階管理層。

The quality assurance/financial unit shall collect the external failure costs incurred by each customer complaint and RMA, and conduct periodic (monthly/quarterly/annual) statistics based on each marketing business to provide to the company's senior management.

5.11.5 當客戶抱怨或RMA退貨發生於使用多少時間，則依據各客戶之使用多少時間相關作業規定執行。

When a customer complaint or an RMA return occurs for how long it is used, it will be implemented in accordance with the relevant operating regulations of each customer for how much time is used.

5.11.6 針對客戶抱怨之處置，若客戶要求以8D報告或指定模式進行時，則依據8D報告問題分析或客戶指定之模式執行之。

For the handling of customer complaints, if the customer requires the 8D report or the specified form to be carried out, it shall be implemented according to the 8D report problem analysis or the customer specified mode.

＊醫療產品退回或是召回必須區隔並標示清楚，如果進行【重工及報廢作業指導書】(6.14)作業，並留下相關紀錄。

如果有適用的法規要求，需符合不良事件報告準則依據《忠告性通知和事故報告程序》(6.13)作業，並留下相關紀錄。

＊Returns or recalls of medical products must be separated and clearly marked, if they are carried out according to [Rework and scrap Work Instructions] (6.14) flow and keep relevant records.

If there are applicable regulatory requirements, it is necessary to comply with the adverse event reporting criteria based on [Advice notices and incident reports procedure] (6.13) work and leave relevant records.

5.11.7 〔矯正行動報告〕（7.3）撰寫流程依照下列步驟方法進行:

The operating process of 〔Corrective Action Report〕(7.3) is according to the 8D method

a. D1客戶反映問題描述 (D1-Customer Problem Description)

客戶抱怨說明資訊或RMA之完整資訊(包括客戶名稱、客戶工廠所在地、抱怨或RMA 料號/系列、不良率/數、不良製令、不良情形、客戶應用製程、使用或測試方式、產品保固失效情形及競爭對手產品在客戶段使用狀況等)。

1.當客戶反映問題，提供的訊息只有文字敘述、照片或影片檔，不需要提供正式分析報告，接獲後的確認動作有：

登錄於客訴統整表(平台)、判斷客訴是否成立，若成立，則品保將訊息通知相關單位並以ERP系統清查庫存，進行損害風險控管，例如序號貼紙位置不正確。

2. 當客戶提供的訊息只有照片或影片檔，需要提供正式報告，獲後的確認動作

有:登錄於客訴統整表(平台)，若成立則品保依照8D報告撰寫流程，蒐集相關型號的生產資訊、留樣品比對確認、將訊息通知相關單位並以ERP系統清查庫存，進行損害風險控管，例如產品品質有異常: 外觀異常，上層貼反了。

3. 當收到客退品品質四課會進行:

3-1. 依照客戶反映問題，提供的訊息與〔RMA申請單〕（7.4）比對清點數量與登錄序號。

3-2. 將清點的結果登錄於RMA 客退品檔案一覽表，並將結果通知行銷業務。

負責單位：品質四課

協助單位：行銷部、資材部、生產部。

b. D2成立改善小組 (D2-Analyze and Improve Team Composition)

1. 當客戶提供的訊息只有照片或影片檔，不需要提供正式分析報告。
電氣功能議題-會通知品質三課、生技課，若有必要會找研發部一起討論。

2. 當客戶提供的訊息只有照片或影片檔，需要提供正式報告，收到RMA客退品品質四課，會依電氣或外觀議題找那些團隊進行，要說明清楚。
品保單位於清點RMA退回品(含醫療產品)完成後24小時內，通知相關單位負責人及該單位主管，並召開會議成立改善小組。
-例如:電氣議題-會找品質三課、生技課進廠分析與改善，有必要會找研發部一起討論。
-例如:外觀議題-會找品質三課、生產部負責主管，有必要會找研發部一起討論。

3.客戶退回需進行重工，會依電氣或外觀議題找那些團隊進行，要說明清楚。
-例如:電氣議題-會找品質三課、生技課進廠評估，有必要會找研發部一起討論。
-例如:外觀議題-會找品質三課、生產部負責主管評估，有必要會找研發部一起討論。

c. D3暫時性的對策實施及確認 (D3-Short Term Action)

1. 對客訴或RMA產品相關製程管制資料及相關品質履歷(首件、巡檢、入庫、出貨品質檢驗記錄及不良樣品/留樣品品質及特採記錄等)進行確認，以找出初步原因，確定受影響範圍，鎖定不良批，並制定臨時對策。

2. 須考量在製品/WIP, 確認留樣品是否有客戶反映相同異常現象，確認庫存品

是否有客戶反映相同異常現象，代理商庫存品與在(路)途品是否有客戶反映相同異常現象。

a. 品保撰寫分析報告前，應先與行銷單位充分溝通，確認報告撰寫方向。對外說明需雙方達成共識，掌握時效並讓客戶滿意。

b. 分析報告撰寫完成後，依流程進行會簽，當行銷單位發現報告需要調整、修改、補資訊等需求，需即時告知並由品保單位協助完成。

c. 行銷單位會簽完成後，即視為同意此份分析報告符合對外說明需求。應婉轉向客戶說明(必要時品保單位應協助說明)，使其滿意分析結果並接受。

負責單位：品保部；

協助單位：生產部、研發部、行銷部。

d. D4原因分析及證實 (D4-Root Cause)

依照電氣或外觀議題:

電氣異常: 品質四課主導召開會議偕同品質三課、生技課一同確認異常品、分析原因。

若退回品分析結果與設計(RD)有關將一併通知。

外觀異常: 品質四課主導召開會議偕同品質三課、生產部一同確認異常品、分析原因。

若退回品與材料有關將一併通知研發材料單位。

尋求生產部、技術團隊進行確認分析驗證計畫後結果。

-例如:電氣驗證計畫-會找品質三課、生技課進廠分析與改善，有必要會找研發部一起確認分析驗證計畫後結果，或重工手法的進行。

-例如:外觀驗證計畫-會找品質三課、生產部，有必要會找研發部一起確認分析驗證計畫後結果，或重工手法的進行。負責單位：改善小組；協助單位：品質二課。

e. D5永久改善行動對策的選擇 (D5-Long Term Action)

電氣異常: 生技課提供改善成長對策，由品質三課確認改善成長對策有效性、落實性。若異常原因與RD相關，將由RD提出改善成長對策。

外觀異常: 生產部提供改善成長對策，由品質三課確認改善成長對策有效性，品質二課負責追蹤改善成長對策落實結果。

若異常原因與研發相關，將由研發部提出改善成長對策。

若異常原因與資材相關，將由資材部提出改善成長對策。

結合客戶應用需求，確認客戶規格、廠內規格，對客戶製程、廠內製程進行分析驗證，通過模擬驗證及不良再現確保找出問題真因。各責任單位結合真因分析結果，提出永久改善對策給品保單位(當影響因素不止一項時，應依各因素影響度及執行先後順序層別改善對策之執行步驟)，品保單位綜合各責任單位改善對策後提出正式改善成長對策，經品保最高權責主管核示後，交行銷單位回覆客戶。

不同責任單位所提對策有衝突或無法銜接時，應由改善團隊之領導人主導協調以確保對策能有效執行。

f. D6永久改善行動實施及效果確認(D6-Corrective Action Effectiveness Verification)

電氣異常: 依據分析真因結果，若是製程參數問題生技提供改善成長對策，由品質三課確認改善成長對策有效性、落實性。若異常原因與研發設計相關，將由研發部提出改善成長對策。

外觀異常: 生產部提供改善成長對策，由品質三課確認改善成長對策有效性，品質二課負責追蹤改善成長對策落實結果。

g. D7避免再發生、系統性預防建議 (D7-Preventive Actions)

1.當導入分析驗證計畫對策或重工手法，可以有效性改善，請當責單位修改或新增標準作業程序/SOP內容，傳簽後由文管中心正式發行，完成標準化。對於驗證確認有效之改善對策，需橫向展開至其它相關產品/過程。

2.標準作業程序/SOP文件正式發行後，由品質二課、品質三課在製程巡檢依據進行稽核確認。

3.涉及產品及過程變更之改善對策應返回 PFMEA文件中進行分析，必要時應對PFMEA及相關工程/品質管制文件(如工程圖面、產品品質管制計劃、作業規範、外觀檢驗規範、產品規格及包裝規範等)進行修訂，作為品質系統持續改善之參考依據，以利經驗之傳承，適用時，此改善經驗應展開至同系列或類似產品及製程。產品與過程變更應依據《設計變更管制程序》之相關規定辦理ECR/ECN變更、驗證、會簽及發行作業，並依規定執行通知客戶並獲得客戶同意。

負責單位：異常責任單位；

協助單位：品保部、生產部、研發部、行銷部。

h. D8請分享教育訓練 (D8-Recognition by Education and training)

每週品質會議，分享客戶的聲音並由異常責任單位進行檢討與改善成長分享。

負責單位：異常責任單位；

協助單位：品質四課。

協助單位：營運處

＊醫療產品退回或是召回必須區隔並標示清楚，如果進行【重工依據重工及報廢作業指導書】(6.14)作業，並留下相關紀錄。

如果有適用的法規要求，需符合不良事件報告準則依據《忠告性通知和事故報告程序》(6.13)作業，並留下相關紀錄。

5.12 客服維修品退回處理流程(The process of the products returned for service repairing):

5.12.1 收到退回品時需確認異常現象是否與客戶描述一致，並檢查有無其它異常現象。若有不相符或其它的異常現象，應第一時間回饋客戶，以避免後續爭議。

When receiving the returned product, it is necessary to confirm whether the abnormality is consistent with the customer's description, and check whether there are other abnormalities. If there is any inconsistency or other abnormalities, it should be informed to the customer as soon as possible to avoid subsequent disputes.

5.12.2 依客戶委託之需求開立重工單，再依據【重工及報廢作業指導書】(6.14)作業，並留下相關紀錄。

Established the rework order according to the customer's request, and then work according to the [Rework and scrap Work Instructions] (6.14), and leave relevant records.

5.12.3 執行維修作業前，需確認新元件的外觀與功能是否正常，軟件版本(F/W)是否與客戶相符。

Before repairing, it is necessary to confirm whether the appearance and function of the components are normal, and whether the software version (F/W) is consistent with the customer requirement.

5.12.4 重工完成的產品，需經過相關單位(生產部、品保部)確認重工品的品質(外觀、功能)。For products completed reworked, the quality (appearance, function) must be confirmed by relevant units (Production Dep., Quality Assurance Dep.).

6.0參考文件：

6.1 倉儲管理程序（QP-207）。
6.2 報廢管理程序（QP-210）。
6.3 銷貨折讓及退回作業指導書（QWI-S0011）。
6.4 AMT 環境有害物質管理準則（QWI-Q0021）。
6.5 觸控螢幕外觀檢驗標準（A00X 或 B00X 或 G00X）。
6.6 客戶服務程序 (QP-205)。
6.7 各型號承認書 (AS-XXXXX-XX)。
6.8 RMA 重工作業指導書(QWI-Q0096)。
6.9 AMT 客戶文件。
6.10 產品鑑別與追溯程序（QP-218）。
6.11 不合格品管制程序（CP-230）。
6.12 設計變更管制程序（QP-212）。
6.13 忠告性通知事故報告程序（CP-250）。
6.14 重工及報廢作業指導書（QWI-P0030）。
6.15 品質(含醫療產品)、環境、能源與職業安全衛生記錄管理程序（CP-247）。

7.0 使用表單：

7.1 RMA 退回分析單（QWF-Q0015）。
7.2 客退品分析報告（QWF-Q0053 or QWF-Q0054）。
7.3 矯正行動報告(QWF-Q0006）。
7.4 RMA 申請單（QWF-Q0013）。
7.5 進料品質異常通知單（QWF-Q0018）。
7.6 庫存轉撥單（QWF-P0039）。
7.7 RMA 領料單（QWF-P0033）。
7.8 出貨通知單（QWF-S0011）。
7.9 RMA 還貨單（QWF-Q0014）。
7.10 廠內重工單 (QWF-M0002) 。
7.11 銷退單 (IWF-S0006) 。
7.12 貨款折讓單 (IWF-S0013) 。
7.13產品召回申請單(QWF-Q0093) 。

7.14 OFM RMA退回分析維修單（QWF-XI002）。

7.15 RMA還貨單(汐止廠使用) (QWF-Q0118) 。