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| **Document intended for the certification body and the lead auditor / 供認證機構和首席審核員使用的文件** | | | | | |
| The name and surname of the auditor | |  | | | |
| 審核員姓名 | |
| Issue date | |  | | | |
| 簽發日期 | |
| Signature of auditor is not required. The certification body accepts this document in word format. | | | | | 不需要審核員簽名。 認證機構接受此文檔的 word 格式。 |
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| Audit evidences (proofs) | | During the audit, the auditor notes the evidence presented-proofs (documents, records) proving the functioning and effectiveness of the management system. All evidence obtained and recorded during the audit must be identifiable, i.e. have a title, document number or edition and date of issue/preparation | | | |
| 審計證據（樣張） | | 在審核期間，審核員記錄證明管理體系功能和有效性的證據（文件、記錄）。 在審計期間獲得和記錄的所有證據必須是可識別的，即有標題、文件編號或版本和發布/準備日期。 | | | |
| Product or service | | A product or service provided as part of the activity submitted for certification | | | |
| 產品或服務 | | 作為提交認證的活動的一部分提供的產品或服務 | | | |
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| **Documented information as part of the client's business** | | **Evidence (proofs) of documented information** | | | |
| **作為客戶業務一部分的文件化信息** | | **文件化信息的證據（證據）** | | | |
| A document confirming the customer's commitment to deliver/transfer a product or service in accordance with the requirements (specification) | | For example:   1. purchase order or contract, (name or number), order or contract date 2. register of orders (contracts)   例如：  1. 採購訂單或合同，（名稱或編號），訂單或合同日期  2.訂單登記（合同） | | | |
| 確認客戶承諾按照要求（規範）交付/轉移產品或服務的文件 | |
| Dowód (dowód) dostawy/przekazania produktu lub usługi zgodnie z wymaganiami odbiorcy (zamawiającego) | | For example:  • final product inspection report,  • certificate or declaration of conformity issued for the product,   * Receipt/delivery protocol   例如：  • 最終產品檢驗報告，  • 為產品頒發的證書或合格聲明，  • 接收/交付協議 | | | |
| 根據接收方（訂購方）的要求交付/轉移產品或服務的證據（證據） | |
| Evidence (proof) of providing complaint handling as part of the supply of a product or service | | For example:  • Complaint register  • Example of an assessed complaint   * Complaint protocol   例如：  • 投訴登記  • 評估投訴示例  • 投訴協議 | | | |
| 作為產品或服務供應的一部分提供投訴處理的證據（證據） | |
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| No. | ISO 9001 requirements | | Evidence of documented information, information - documents, traceable records, explanation (if applicable) | | |
| 不。 | ISO 9001 要求 | | 文件化信息的證據，信息 -文件、可追溯記錄、說明（如適用） | | |
| **4.** | **Context of the organization** | | | **组织的背景** | |
| 4.1 | Understanding the organization and its context | | | Example:  Record in the Quality Book of ??  SWOT analysis of ??  例子：  記錄在質量手冊中？？  SWOT分析?? | |
| 了解組織及其背景 | | |
| 4.2 | Understanding the needs and expectations of interested parties | | | Example:  Record in the Quality Book of ??  SWOT analysis of ??  例子：  記錄在質量手冊中？？  SWOT分析?? | |
| 質量管理體系範圍的定義 | | |
| 4.3 | Definition of the scope of the quality management system | | | Example:  Quality Book of ??  例子：  質量書?? | |
| 質量管理體系範圍的定義 | | |
| 4.4 | Quality management system and its processes | | | Example:  Quality Manual, p. 4.4,  Process map  Established main process: ??/  Governance processes established: ??  Support processes established: ??  例子：  質量手冊，第 4.4 頁，  流程圖  建立主進程：??/  已建立的治理流程： ??  建立的支持流程： ?? | |
| 質量管理體系及其流程 | | |
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| **5.** | **Leading** | | | **领导** | |
| 5.2 | Leadership and commitment | | |  | |
| 領導力和承諾 | | |
| 5.2 | Quality policy | | |  | |
| 質量方針 | | |
|  | Roles, responsibilities and permissions in the organization | | |  | |
| 組織中的角色、職責和權限 | | |
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| **6.** | **Planning** | | | **策划** | |
| 6.1 | Actions relating to risks and opportunities | | |  | |
| 與風險和機遇相關的行動 | | |
| 6.2 | Quality goals and planning to achieve them | | |  | |
| 質量目標和實現這些目標的計劃 | | |
| 6.3 | Planning changes | | |  | |
| 規劃變更 | | |
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| **7.** | **Assistance** | | | **支持** | |
| 7.1 | Resources | | |  | |
| 資源 | | |
| 7.2 | Competence | | |  | |
| 權限 | | |
| 7.3 | Awareness | | |  | |
| 意識 | | |
| 7.4 | Communication | | |  | |
| 溝通 | | |
| 7.5 | Documented information | | |  | |
| 文件化信息 | | |
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| **8.** | **Organization** | | | **运行** | |
| 8.1 | Planning and supervision of operational activities | | |  | |
| 業務活動的規劃和監督 | | |
| 8.2 | Product and service requirements | | |  | |
| 產品和服務要求 | | |
| 8.3 | Design and development of products and services | | |  | |
| 產品和服務的設計和開發 | | |
| 8.4 | Supervision of processes, products and services provided from outside | | |  | |
| 對外部提供的過程、產品和服務的監督 | | |
| 8.5 | Production and service delivery | | |  | |
| 生產和服務交付 | | |
| 8.6 | Product and service release | | |  | |
| 產品和服務發布 | | |
| 8.7 | Supervision of non-compliant outputs | | |  | |
| 監督不合規輸出 | | |
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| **9.** | **Evaluation of Performance** | | | **绩效评价** | |
| 9.1 | Monitoring, measurement, analysis and evaluation | | |  | |
| 監測、測量、分析和評價 | | |
| 9.2 | Internal audit | | |  | |
| 內部審計 | | |
| 9.3 | Management review | | |  | |
| 管理評審 | | |
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| **10.** | **Improvements** | | | **改进** | |
| 10.1 | Identifying and selecting opportunities for improvement and implementing necessary actions to meet requirements and increase customer satisfaction | | |  | |
| 識別和選擇改進機會並實施必要的措施以滿足要求並提高客戶滿意度 | | |
| 10.2 | Nonconformities and corrective actions | | |  | |
| 不符合項和糾正措施 | | |
| 10.3 | Continuous improvement of the suitability, adequacy and effectiveness of the quality management system | | |  | |
| 持續改進質量管理體系的適宜性、充分性和有效性 | | |