QMS CERTIFICATION

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ARE YOU READY FOR ISO 9001:2015 CERTIFICATION?

ITEM	ELEMENT	9001	COMPLIANCE (Y/N)	COMMENTS AND EVIDENCE
1	Understanding the organization and its context: Have the external and internal issues relevant to the strategic purpose and direction been determined? Is there evidence of the monitoring and critical analysis of information on these external and internal issues?	4.1		
2	Have the needs and expectations of stakeholders been defined, with monitoring and critical analysis?	4.2		
3	Has the scope of the QMS been determined including external and internal issues, relevant stakeholder requirements, and the organization's products and services? Is the scope still available as documented information?	4.3		
4	Have QMS processes been established, implemented, or maintained? Is there evidence of continuous improvement of established processes?	4.4.1		
5	Is there documented information for the QMS and its processes maintained and retained?	4.4.2		
6	Has Senior Management assured the client of the applicable legal/regulatory requirements? Are these determined, understood, and achieved consistently? Have the risks and opportunities been determined and managed? Is there a focus on increasing customer satisfaction?	5.1.2		
7	Is the quality policy appropriate to the purpose and context of the organization? Does politics support your strategic direction? Does it provide a framework for defining quality objectives? Does it include a commitment to meet the applicable requirements and continuous improvement of the QMS?	5.2.1		
8	Are responsibilities and authorities for relevant functions assigned, communicated, and understood? Including process inputs, performance reports, the promotion of customer focus and QMS integrity is maintained.	5.3		
9	Have the risks and opportunities been determined? Including intended results to be achieved and increase desirable effects, reduce/prevent unwanted effects, and achieve improvement.	6.1.1		
10	Are the objectives set for the relevant functions and levels? Is the documented information kept?	6.1.2		
11	Were certain necessary changes made in a planned manner? (purpose of changes, consequences, integrity of the QMS, availability of resources, and allocation or reallocation of responsibilities/authorities).	6.3		
12	Are there resources determined and provided by the management of the QMS? Considerations made for the capabilities and limitations of resources, which is required to be obtained from external providers.	7.1.1		

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13	Is there a determination of the necessary people for the effective implementation, operation and control of the QMS?	7.1.2		
14	There is determination, provision and maintenance of the appropriate infrastructure.	7.1.3		
15	Is there determination, provision and maintenance necessary of the environment for the operation of your processes, to achieve the conformity of products and services?	7.1.4		
16	Is there determination and provision of resources necessary to ensure the validity and reliability of monitoring and measurement results? When used to verify the conformity of products and services.	7.1.5.1		
17	Is it in compliance with calibration/verification of measuring equipment, including safeguards to prevent damage and deterioration?	7.1.5.2		
18	Has the necessary knowledge been determined for the operation of the available processes and maintenance? Including access to additional knowledge and necessary updates will be acquired.	7.1.6		
19	Have the necessary skills been determined? Competent people based on education, training, experience, the evaluation of the effectiveness of the actions taken and information documented and maintained as evidence of competence.	7.2		
20	Have internal/external communications been determined, including what will be communicated, when, with whom, how and who will communicate?	7.4		
21	Has the organization ensured control of the documentation? Is there an appropriate identification and descriptions, formats and is it reviewed/approved for adequacy?	7.5.2		
22	Is there control of distribution, access, retrieval, use, storage, preservation, change control, retention, and disposition of documented information?	7.5.3.2		
23	Have processes been established for the planning, implementation and control of product/service supply? Including the determination of requirements, acceptance criteria, resources and necessary documentation.	8.1		
24	Have the requirements of products/services offered been determined, does it include regulatory requirements, organizational and legal requirements to ensure the order of products/services offered can be met?	8.2.2		
25	In design and development, is there a process established, implemented and maintained to ensure the subsequent provision of products and services?	8.3		
31	Are externally provided processes, products and services in accordance with the established requirements? Including determination of controls.	8.4.1		
32	Is there implementation of production and service provision under controlled conditions? Including availability of documented information.	8.5.1		
33	Is there identification of outputs to ensure the conformity of products and services? Including unique identification and traceability requirement.	8.5.2		
34	Are there established processes for controlling ownership owned by external customers or providers?	8.5.3		

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35	Is there preservation of outputs during production and service delivery to ensure compliance with requirements, including identification, handling, contamination control, packaging, storage, transmission or transportation, and protection?	8.5.4		
36	Were certain post-delivery activities associated with the products and services?	8.5.5		
37	Is there critical analysis and change control for production and service delivery? Including retention of documented information, describing the results of critical analyses of changes	8.5.6		
38	Is there documented information about the release of products and services? Including evidence of compliance with acceptance criteria and traceability of person(s) authorized for release.	8.6		
39	Are outputs that do not conform to your requirements identified and controlled?	8.7.1		
40	Is there retention of documented information that describes the non-compliance, actions taken, concessions obtained, and identifies the authority that decided the action?	8.7.2		
41	Is there a determination of monitoring and measurement requirements, performance evaluation methods and results?	9.1.1		
42	Is there monitoring of customer satisfaction and determination of the method to obtain and critical analysis of the information?	9.1.2		
43	Is analysis and evaluation of appropriate data and information arising from monitoring and measurement established?	9.1.3		
44	Have planned, established and maintained audit programs been established? Retained documented information such as program evidence and audit results.	9.2.2		
45	Is critical analysis of the QMS performed at the planned periodicity to ensure continuous adequacy, applicability and effectiveness, and alignment with the strategic direction of the organization?	9.3.1		
46	Are opportunities for improvement determined and implemented to meet customer requirements and increase customer satisfaction?	10.1		
47	Non-compliance and corrective actions, are critically analyzed and evaluated for evaluation of effectiveness, and are documented information retained?	10.2		
48	Is there continuous improvement of the QMS? Including adequacy and effectiveness, consideration of the results of analysis, evaluation and outputs of critical analysis by Management.	10.3		