

D 108: DEMO OF CE TECHNICAL FILE DOCUMENT KIT

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Chapter-1.0 CONTENTS OF CE TECHNICAL FILE DOCUMENT KIT

(More than 40 document files)

A. The entire documentation kit has 46 chapters as below.

CE TECHNICAL FILE code D108



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B. Documentation: -

Our document kit is having sample documents required for CE certification as listed below. **All documents are in word and you can edit it.** You can do changes as per your company need and **within 3 days your entire documents** with all necessary controls are ready and our many organization are certified globally in 1st trial with the help of our documents from any stringent certification audit.

Under this directory further files are made in word Document as per the details listed below. All the documents are related to any kind of manufacturing/process industry. Our technical file is sample templates and as per applicable directives company needs to make their own documents.

1. CE Technical File: -

It is cover sample details like Scope of Products under CE Certifications, Company Profile, Quality, Control and Manufacturing Facilities, Manufacturing Flow chart, Descriptions –Technical Specification, Bill of materials, Product Test Reports, Product Validation Records, equipment operations and maintenance, Identification and Traceability, Handling, storages Packaging, Preservation and Delivery, final product release, receiving inspection, deviation, product recall, post market surveillance, Validation, labeling, CE Marking, risk analysis, Failure mode effective control analysis, Handling of Non–conformities, Risk analysis, Materials specifications for various products, Quality Plan, Packaging qualification (Plan & Report), Test reports from external laboratories, Product applications, Products labels, Use instructions, Declaration of conformity, List of Harmonized Standards for making CE Technical File etc. The index of content of CE technical file is given below. Based on our sample company needs to make own documents based on their products

INDEX OF TECHNICAL FILE

1. Index
2. Scope of Products under CE Certifications
3. Company Profile
4. Quality Control and Manufacturing Facilities
5. Manufacturing Flow chart
6. Product Descriptions –Technical Specification
7. Bill of materials
8. Product Drawings
9. Product Test Reports
10. Product Validation Records
11. Procedure for controlled environment conduct (with contamination control
12. Procedure for facility maintenance
13. Procedure for equipment operations and maintenance
14. Procedure for batch records
15. Procedure for Identification and Traceability

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16. Process for Handling, storages Packaging, Preservation and Delivery
17. Procedure for final product release
18. Procedure for receiving inspection
19. Process for deviation
20. Procedure for retain samples
21. Procedure for stability studies
22. Process for product recall
23. Procedure for post market surveillance
24. Process for Validation
25. Procedure for labeling
26. Procedure for CE Marking
27. Procedure for risk analysis
28. Procedure for Failure mode effective control analysis
29. Procedure for product classification and conformity root (Only sterile products)
30. Procedure of Handling of Non-conformities
31. Risk analysis
32. Materials specifications for various products
33. Quality Plan
34. Cleaning validation (Plan & Report)
35. Sealing validation (Plan & Report)
36. ETO validation (Plan & Report)
37. Packaging qualification (Plan & Report)
38. Reports of bio burden
39. Reports of sterility. Acute toxicity and pyrogen
40. Test reports from external laboratories
41. Product applications
42. Products labels
43. Use instructions
44. Declaration of conformity
45. List of Harmonized Standards
46. Essential safety requirements

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Chapter-2.0 ABOUT COMPANY

Global manager group is a progressive company and promoted by a group of qualified engineers and management graduates having rich experience of 20 years in certification consultancy and management areas. The company serves the global customers through on-site and off-site modes of service delivery systems. We offer a full range of consulting services geared towards helping all types of organizations to achieve competitiveness, certifications and compliance to international standards and regulations. So far we had **more than 1200 clients in more than 45 countries**. Our ready made training and editable document kit helps the client in making their documents easy and make them complying to related system standard faster.

1. Our promoters and engineers have experience of **more than 1200 companies** globally for management training, system series consultancy. We had clients **in more than 45 countries**.
2. Highly qualified 40 team members (M.B.A., Degree engineers) and owner is having rich professional experience (since 1991).
3. We have 100% success rate for system series certification of our clients from reputed certifying body and branded image and leading name in the market.
4. Suggest continual improvement and cost reduction measures as well as highly informative training presentations and other products gives payback within 2 months against our cost.
5. So far more than 50000 employees are trained by us in ce mark certification.
6. We had spent more than 60000 man-days (170 man years) in preparing system documents and training slides.

Global Manager Group is committed for:

1. Personal involvement & commitment from first day
2. Optimum charges
3. Professional approach
4. Hard work and update the knowledge of team members
5. Strengthening clients by system establishment and providing best training materials in any areas of management to make their house in proper manner
6. To establish strong internal control with the help of system and use of the latest management techniques

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Chapter-3.0 USER FUNCTION

3.1 Hardware and Software Requirements

A. Hardware: -

- Our document kit can be better performed with the help of P3 and above computers with a minimum 10 GB hard disk space.
- For better visual impact of the power point Documentation you may keep the setting of colour image at high colour.

B. Software used in Documentation kit

- Documents written in word 98 and window 2000 programs. You are therefore required to have office 2000 or above with word 98 and power point

3.2 Features of Documentation kit: -

- Contains all necessary documents as listed above and comply with the requirements of system standards
- Written in Plain English
- It will save much time in typing and preparation of documents alone.
- User-friendly and easy to learn.
- Developed under the guidance of experienced experts.
- Provides model of a Management system that is simple and free from excessive paperwork

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Chapter-4.0 BENEFITS OF USING OUR DOCUMENT KIT

1. By using these documents, you can save a lot of your precious time while preparing the CE Technical File documents.
2. Take care for all the section and sub sections of CE Technical File standard and helps you in establishing better system.
3. Document kit enables you to change the contents and print as many copies as you need. The user can modify the documents as per their industry and create own CE Technical File documents for their organization
4. Readymade templates and sample documents are available which can reduce your time in document preparation.
5. Save much time and cost in document preparation.
6. The audit questions helps in making perfect audit checklist.

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