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**Chapter-1.0 CONTENTS OF CE Mark Technical File
(Some time also called as Technical Construction File)**

This editable documentation kit has 2 main directories in Word, as below:

Sr. No.	Directory	Details of Documents
1.	**Technical File**	**47 Files in MS Word**
2.	**Blank Formats / Templates** **Name of departments**	**23 Blank Formats in MS Word / excel**
	Management system (SYS)	05 formats in MS Word
	Production (PRD)	05 formats in MS Word
	Marketing (MKT)	02 formats in MS Word
	Engineering (ENG)	03 formats in MS Word
	Quality control (QCD)	02 formats in MS Word
	Service (SER)	02 formats in MS Word
	Design and development (DND)	01 format in MS Word
	Stores (STR)	01 format in MS Word
	Sample DoC	02 formats in MS Word

Total 70 files in editable form; Quick Download by e-delivery

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Documentation package:

Our documentation kit (Technical file) contains sample documents required for CE certification as listed below. **All documents are in MS Word files and you can edit them.** You can make changes as per your organization's need and **within few days your entire Technical File** with all necessary controls will be ready. In the Technical File, documented information (processes described in individual file, etc.) are required a few places only. But for making the system better, we have provided many editable templates from which a user can select templates as per their own requirement and make some minor changes in them to make own system. Two types of documented information are provided in this kit, as listed below:

1. **Maintain documented information (Technical File with individual processes etc.)**
2. **Retain documented information (Forms / Templates)**

Under the main directories, further files are provided in MS Word document as per the details given below.

1. Technical File (46 Different processes as required in CE Mark Technical File):

It is a comprehensive technical file, which can be used by any type of products. User has to just check the applicability of relevant documents, requirements of relevant directives and then can modify to suit the product under the certification. The content of the comprehensive technical file are given on the next page;

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(A) Table of Contents – Technical File

Sr. No.	Title of document / document name	Nos. of pages
1.	Index	2
2.	Scope of Products under CE Certifications	1
3.	Company Profile	1
4.	Quality Control and Manufacturing Facilities	3
5.	Manufacturing Flow chart	1
6.	Product Descriptions –Technical Specification	1
7.	Bill of materials	1
8.	Product Drawings	1
9.	Product Test Reports	2
10.	Product Validation Records	1
11.	Procedure for controlled environment conduct (with contamination control	1
12.	Procedure for facility maintenance	1
13.	Procedure for equipment operations and maintenance	1
14.	Procedure for batch records	1
15.	Procedure for Identification and Traceability	2
16.	Process for Handling, storages Packaging, Preservation and Delivery	2
17.	Procedure for final product release	1
18.	Procedure for receiving inspection	1
19.	Process for deviation	1
20.	Procedure for retain samples	1
21.	Procedure for stability studies	1
22.	Process for product recall	1
23.	Procedure for post market surveillance	2
24.	Process for Validation	2

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Sr. No.	Title of document / document name	Nos. of pages
25.	Procedure for labeling	1
26.	Procedure for CE Marking	2
27.	Procedure for risk analysis	2
28.	Procedure for Failure mode effective control analysis	3
29.	Procedure for product classification and conformity root (Only sterile products)	2
30.	Procedure of Handling of Non–conformities	2
31.	Risk analysis	2
32.	Materials specifications for various products	1
33.	Quality Plan	2
34.	Cleaning validation (Plan & Report)	2
35.	Sealing validation (Plan & Report)	2
36.	ETO validation (Plan & Report)	2
37.	Packaging qualification (Plan & Report)	1
38.	Reports of bio burden	1
39.	Reports of sterility. Acute toxicity and pyrogen	1
40.	Test reports from external laboratories	1
41.	Product applications	1
42.	Products labels	1
43.	Use instructions	1
44.	Declaration of conformity	1
45.	List of Harmonized Standards	1
46.	Essential safety requirements	1

The content with the red fonts are applicable of product falls under Medical Device Directives only.

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2. Blank sample formats for all the departments (23 sample formats)

This directory includes sample copy of blank forms that are required to maintain records as well as establish control and create system in the organization to comply with the requirements of CE Mark. The samples are given for the users as a guide to follow. The organization is free to change the same to suit their own requirements. The blank formats can be used as templates. A total of 23 blank formats are provided as per the list given below.

List of blank formats

1.	Calibration Status of Instrument / Equipment	2.	Master List of Records
3.	Audit Non–Conformity Report	4.	Corrective Action Report
5.	Preventive Action Report	6.	Production Plan
7.	Job Card	8.	Disposal of Non–Conforming Products
9.	List of Equipments	10.	List of Instrument
11.	Customer Feed Back Form	12.	Customer Complaint Report
13.	Breakdown History Card	14.	Preventive Maintenance Schedule
15.	Equipment wise Preventive Maintenance Check Points (Total 8 different checkpoints)	16.	Final Inspection Report
17.	Risk Analysis	18.	Installation And Commissioning Report
19.	Service Report	20.	Bill of Materials
21.	Preservation Assessment	22.	Sample Declaration of Conformity–1
23.	Sample Declaration of Conformity–2		

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Chapter-2.0 ABOUT COMPANY

Documentation Consultancy is a progressive company promoted by a group of qualified engineers and management graduates having rich experience of over 25 years in ISO 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, certification, accreditation and compliance to international standards and regulations. So far, we have **more than 2700 clients in more than 36 countries**. **Our readymade training kit and editable documentation kit help the clients in making their documents with ease and complying with the related ISO standard faster.**

1. Our promoters and engineers have rich experience of providing management training and ISO series consultancy for **more than 2700 companies** globally. We have clients **in more than 36 countries.**
2. We are a highly qualified team of 80 members (M.B.A., Degree Engineers). Our Director has rich professional experience in this field (since 1991).
3. We have 100% success rate in ISO series certification for our clients from reputed certifying bodies. We possess a branded image and are a leading name in the global market.
4. We suggest continual improvement and cost reduction measures as well as provide highly informative training presentations and other products that give you payback within 2 months against our cost.
5. So far, we have trained more than 50000 employees in ISO series certification.
6. We have spent more than 60000 man-days (170 man-years) in the preparation of ISO documents and training slides.

Documentation Consultancy is committed for:

1. Personal involvement and commitment from the day one
2. Optimum charges
3. Professional approach and globally helped many companies for this standard.
4. Hard work and updating 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. Establishing 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 documentation kit can better perform with P4 and higher computers with a minimum of 10 GB hard disk space.

- For better visual impact, you may keep the setting at high color.

B. Software

- Documents are written in MS-Office 2007 and Windows XP programs. You are, therefore, required to have MS-Office 2007 or higher versions with Windows XP.

3.2 Features of Documentation kit

- The kit contains all necessary documents as listed, and complies with the requirements of system standards.

- The documents are written in easy to understand English language.

- This kit will save much time in typing and preparing your documents at your own.

- The kit is user-friendly to adopt and easy to learn.

- The contents of this kit are developed under the guidance of experienced experts.

- The kit provides a model of the management system that is simple and free from excessive paperwork.

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Chapter-4.0 BENEFITS OF USING OUR DOCUMENTATION KIT

1. By using these documents, you can save a lot of your precious time while preparing the CE Mark Technical File.

2. The kit takes care of all requirements for CE Mark Technical File and helps you to establish better system.

3. This documentation kit enables you to change the contents and print as many copies as you need. The users can modify the documents as per their product and relevant EU Directives.

4. It will save much cost in document preparation.

5. You will get a better control in your system due to our proven formats.

6. You will also get a better control in your system as our proven documents and templates are developed under the guidance of experts and globally proven consultants. The team has a rich experience of more than 25 years in the ISO consultancy, CE Mark and accreditation.

7. Our products are highly sold across the globe and are used by many multinational companies. They have got total satisfaction as well as experienced value for money.

8. In the preparation of documentation kit, our team has verified and evaluated the entire content at various levels. More than 1000 hours have been spent in the preparation of this documentation kit.

9. The entire kit is prepared by a globally proven team of leading ISO consultants.

Chapter-5.0 METHOD OF ONLINE DELIVERY

On completion of the secured purchase, we provide a username and password to download the product from our FTP server. We provide instant online delivery of the kit to the users by sending an e-mail of username and password.

For purchase, Click Here ➡ BUY

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