



The seminar will begin
in a few minutes

Understanding CE

Presented By:



William (Bill) Bisenius – NCE/NCT
billb@CertifiGroup.com
CertifiGroup, Inc.
www.CertifiGroup.com



Understanding CE



Section I

What is the
CE Mark?

Compliance – By Country

- US,
- Canada,
- European Union,
- All other International Countries

What Is the European Union?

1

Common Market



**No
Trade Barriers
within the
EU**





1 Giant Market

**400 Million
Consumers
& Growing!**



EU Oversight

- Euro Currency €
- Regulatory Compliance -
CE Mark 
- Rail System Interoperability
- Merger Approvals
- Food Safety
(i.e. radiated meat ban)

CE Mark Purpose

- CE mark indicates compliance with at least one EU “Directive”
- See the Declaration of Conformity (DoC) to identify the Directives



Countries Requiring the CE Mark

- Austria
- Belgium
- Bulgaria
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary

Countries Requiring the CE Mark

- Iceland
- Ireland
- Italy
- Latvia
- Liechtenstein
- Lithuania
- Luxemburg
- Malta
- Norway
- Poland
- Portugal
- Romania

Countries Requiring the CE Mark

- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Turkey
- United Kingdom

**What Are The
Realities
of the CE Mark?**

**You
Must
Comply**

Don't Comply?



Border checks

: Product refused

: Product impounded

Falsify Compliance

- Fines and Imprisonment
- Blacklisting
- Nullifies Business Insurance

The “Rat” is Watching

Competitor complaint is
#1 method of enforcement



Other Countries

- EN standards are based on IEC
- IEC standards accepted
Internationally

International Compliance

- Compliance vs. Certification
- Mandatory Certification?
- Asia, South America, India = Compliance with IEC standards
- Russia = Compliance with IEC plus GOST-R Certification

Compliance – By Country

<u>Country</u>	<u>Standards</u>	<u>Certification</u>
US	UL	“NRTL”
Canada	CSA	“C”
EU	EN	NB Required?
International	IEC	? - By country



Summary Section I

What is the
CE Mark?



Section II

CE Mark Compliance Process

CE Mark Purpose

- CE mark indicates compliance with at least one EU “Directive”
- See the Declaration of Conformity (DoC) to identify the Directives



Methods of Compliance

- Must meet applicable Directives
- Directives refer to Standards,
- Compliance with Standard not mandated,
- Compliance with standard insures compliance with Directive

Methods of Compliance

Self Declaration

VS.

Notified Body (NB)

Methods of Compliance

- Self Declaration = Low Risk Products
- Notified Body = High Risk Products
- Notified Body = exceptions, interpretations, official decisions, approval for MDD, ATEX, PED, others
- Notified Body $\approx$ CE “certification”

CE Mark Process

Handout –
Steps to Apply the CE Mark

CE

Process Summary

- 1) Identify Directives
- 2) Identify Standards
- 3) Self-Declaration vs. Notified Body
- 4) Verify Compliance - prepare TRF's
- 5) Prepare Technical Construction File
- 6) Create Declaration of Conformity
- 7) Apply CE Mark

Identifying Directives

- 1) Review list of EU Directives,
- 2) Identify applicable Directives,
- 3) Verify scope of each Directive,
- 4) Official decisions - European
“Notified Body” (NB) only
- 5) Directive Review – part of TCF

Identifying Standards

- 1) Review the list of Standards for each applicable Directive,
- 2) Identify applicable Standards and effective dates,
- 3) Verify the product meets the scope of each Standard,

Identifying Standards

- European Standards (EN)
- International Standards (IEC & ISO)
- End Product Standards vs.
Component Standards

Verifying Compliance

- Construction Requirements
- Testing Requirements
- Documentation Requirements
 - : Labeling
 - : Manuals
 - : Translation
- Compliance Report (TRF)

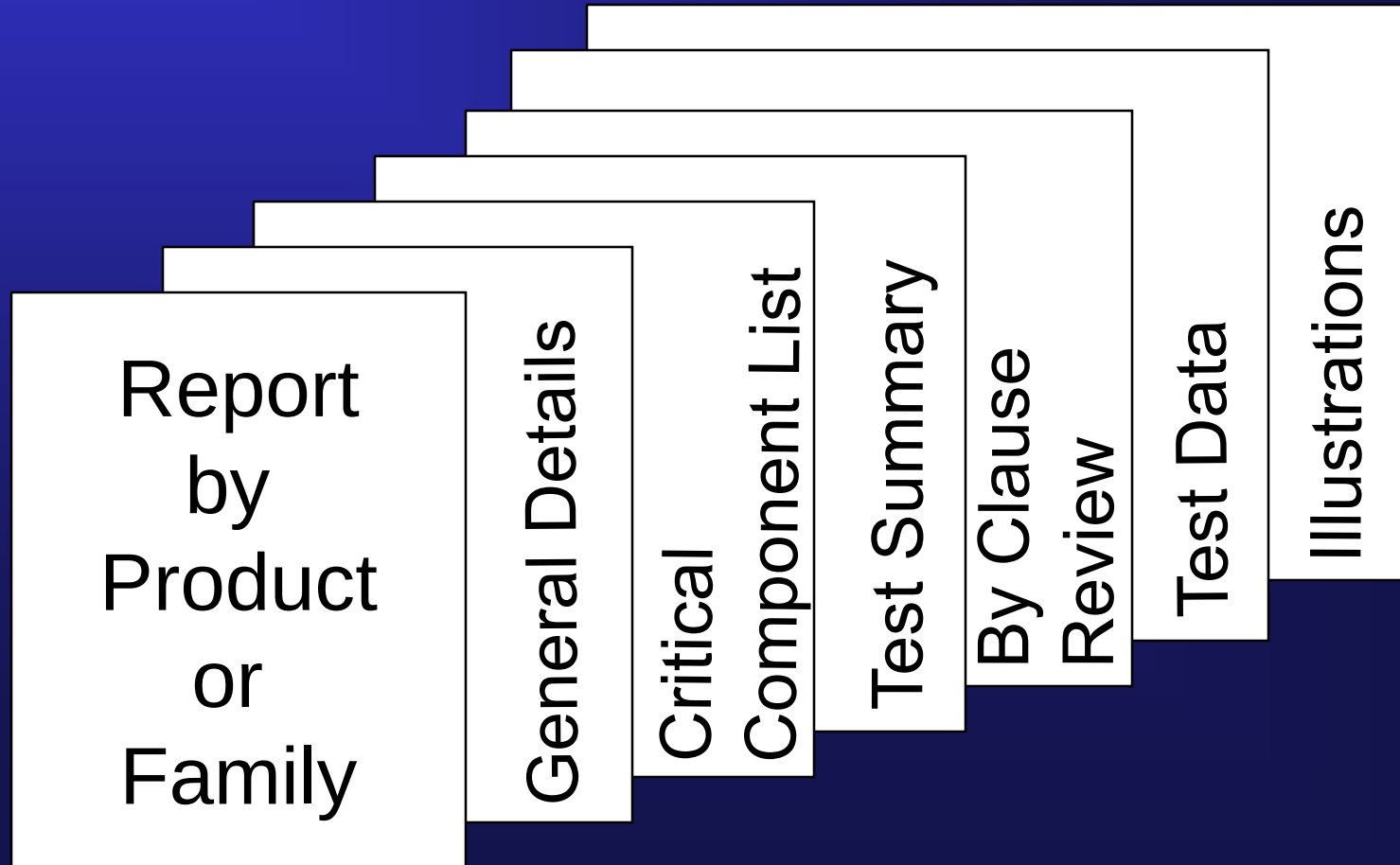
CE Compliance Report

Purpose

- Details how the product complies - clause by clause for each standard
- Product elements for continued compliance - critical component list, schematics, mechanicals, photo's
- Test results

CE Compliance Report

Format



CE Compliance Report

Format

Clause	Requirement	Results			Comments
		Does not apply	Pass	Fail	
4.4	Testing in SINGLE FAULT CONDITION	()	(x)	()	See details in clauses 4.4.2.4 and 4.4.2.6.

Technical Construction File

Format

Everything to show CE compliance by product or product family:

- Directive & Standard Review,
- Copy of DoC,
- Compliance Reports,

Technical Construction File

Format

Includes product construction details and maintaining compliance:

- BOM, Schematics, Diagrams,
- Engineering Decisions & ECO's,
- Revision/Addition Compliance Review

Technical Construction File

Format

It does not need to be printed format:

- It can be an electronic file,
- Must be able to provide to authorities within 48 hours of request (FedEx or e-mail)

CE Process Results

- Maintain TCF,
- Include DoC with each product,
 - o Copy in back of manual,
 - o Copies with Packing Slip

Declaration of Conformity

- Company letterhead,
- Model #,
- Name & address,
- Statement of conformity,
- Product description,

Declaration of Conformity

- Declaration statement,
- List of Directives & Standards to which the product complies,
- NB details if applicable,
- Signature of a Corporate Officer

Declaration of Incorporation

- Machinery Directive ONLY
- Components that cannot be evaluated without the end product
- Similar to DoC with statement pushing compliance to the end product
- No CE mark permitted

CE of Components

- Over the counter parts must be CE
- Other components “may” be CE
- DoI - cannot be CE marked
- Avoid selling your customer a problem – verify compliance
- CE can help sell the component

CE Mark Tips

- CE mark in the manual,
- CE mark on the packaging,
- Multiple copies of the DoC with the shipment
- Advertise CE compliance

Maintaining Compliance

When

- Changing Regulations
 - : New Directives,
 - : More countries in EU
- Changing Standards
 - : New amendments & particulars
 - : DOA - new, DOW – update old

Maintaining Compliance

How

- Changing Products
 - : Verify compliance to standards,
 - : Update needed to report?
 - : Notify NB?
- Record Keeping
 - : 10 years

Tools for Performing CE

- Education,
- Standards ,
- Compliance Equipment,
- Compliant Components,
- Compliance Labels/Symbols

Handout – CE Resource List



Summary Section II

CE Mark
Compliance Process



Section III

The CE Directives

Identifying Directives

Handout –
List of Directives Worksheet

EMC

Low Voltage (Safety)

Machinery

ATEX

Pressure Equipment

Simple Pressure Vessel

RoHS - REACH

WEEE

EMC Directive

- EMC (Electro-Magnetic Compatibility)
= insure electrical interference
from your product is below
limits.
- Immunity = ability to resist
electrical problems caused by
other products

EMC Directive

- Radiated Emissions,
- Conducted Emissions,
- ESD
- EFT
- Surge

EMC - Components

- Don't be the source of the problem
= Immunity considerations
- Test with simulated system
- Outdoor environment electrical
problem sources (i.e. lightning)
- Sensors = entry point for trouble

EMC Good Practices

- Shielded cables
- Grounding
- Grounded enclosure, no vents
- Plastic enclosures require special considerations
- ESD resistant operator interfaces

Low Voltage Directive

- Product Safety Requirements
- Electrical Products
- Requirements:
 - o Construction,
 - o Markings,
 - o Instructions,
 - o Testing: Electrical, Mechanical, & Environmental

Machinery Directive

- Products where the significant safety hazard is a moving part
- Machinery & partly completed machinery
- Risk Assessment based process
- DoC or DoI options for components and sub-assemblies

Machinery Directive

- Base Standard: EN60204
- Plus particular and collateral standards = hundreds to review
 - o Feature/component/hazard driven,
 - o For the end product, much of the process can be identifying all the different standards that apply

ATEX Directive

NB

- Products operated in a “Hazardous” environment vs. “Ordinary Location”
- “Classified” area = Division/Class, Zone/Class specified
 - o US = Class/Division (i.e. Class I, Div 1)
 - o EU = Zone/Division (i.e. Zone 1, Div 1)
 - o Class $\neq$ Zone
- AHJ specified (via customer)

ATEX Directive

NB

- Additional requirements to general product directive (i.e. LVD or MD)
- “Path to Compliance” is the question:
 - o Intrinsically Safe,
 - o Explosion Proof,
 - o Encapsulated,
 - o Non-incendive,
 - o Pressure/Purge,

Pressure Equipment (PED)

NB

- Maximum Pressure is > 0.5 bar
- Gases, dissolved gases, liquids, vapors, with or without solids.
- Group 1 = dangerous fluids, Group 2 = other fluids
- Vessels & piping included
- Requirements in the Directive

Simple Pressure Vessel

- Produced “in series”
- Vessels > 0.5 bar but < 30 bar
- Non-alloy steel or non-alloy Al,
- Welded construction,
- Contains air or nitrogen (recast),
- Not intended to be fired

Simple Pressure Vessel

- Cylindrical or dished ends,
- $PS \times V \leq 10,000 \text{ bar-L}$ (Pressure x Volume)
- Min. Temp 50°C,
- Max. Temp 300°C Steel, 100°C Al
- Vessel Markings per Annex III

Simple Pressure Vessel

NB

- $PS \times V \leq 50 \text{ bar-L}$
 - o Meet designed & manufactured to sound engineering practices in one Member State
- $PS \times V > 50 \text{ bar-L}$
 - o Construction requirements per Annex I
 - o Notified Body required per Annex II

RoHS II

- Restriction of Hazardous Substances in Electrical and Electronic Equipment,
- Limit heavy metals – lead, mercury, hexavalent chromium, cadmium
- Affects solder, components, flame retardants
- Test to verify = XRF analyzer

REACH

- Regulation, Evaluation, Authorization, and Restriction of Chemicals Directive
- Limit/ban SVHC's = Substances of Very High Concern
- 29 SVHC's + 14 additional proposed,
- See REACH Directive

Good Material Practices

- Verify all materials are RoHS & REACH compliant
- Spec sheet with symbol is enough
- DoC showing compliance is best
- Your DoC showing compliance will satisfy customers
- Plastics, solders, circuit boards, batteries, etc.



Summary Section III

The CE Directives



Section IV

The Product Certification Process

First Step to Certification

- Identify the countries to market,
- Suggest conservative approach - far more efficient/cost effective to do all countries simultaneously,
- LVD or Machinery Directive?
- RoHS/REACH

CE Process Options

- Do-it-Yourself,
- Use a 3rd party agency,
- Use a 3rd party first as an example,
- Do-it-Yourself + on-call consultant,



Summary Section IV

The Product Certification Process



Conclusion - Understanding CE



THANK YOU for your interest and participation

Presented by
Bill Bisenius – NCE/NCT
billb@CertifiGroup.com
CertifiGroup, Inc.
www.CertifiGroup.com

**Please let us know if you can assist you with your
Compliance needs = Test Equipment & Calibration,
Training, Consulting, Testing,
& Certification Services**