

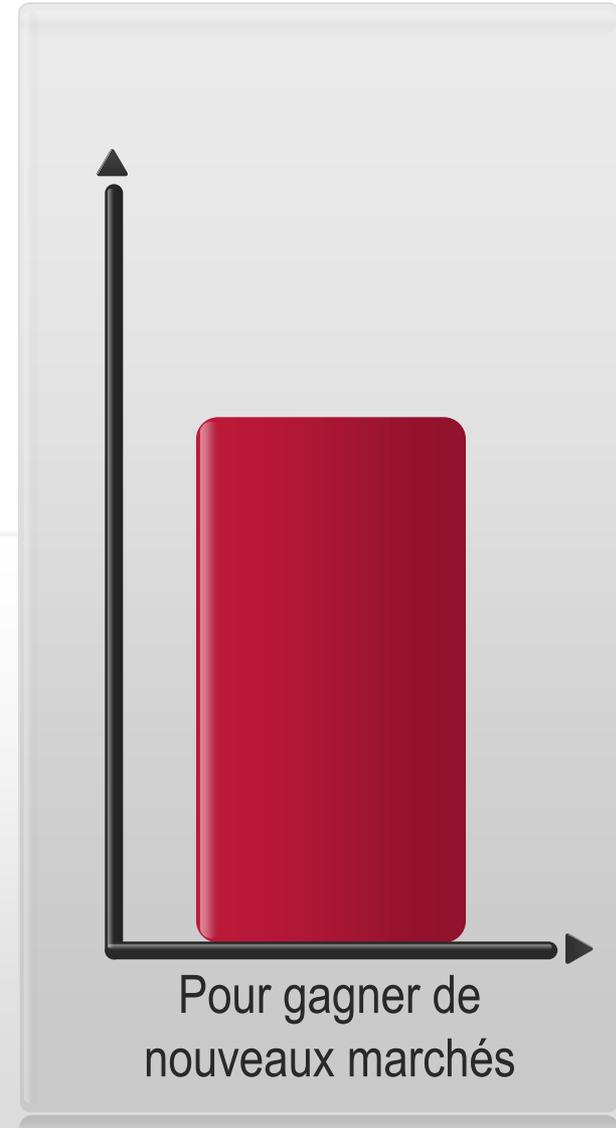
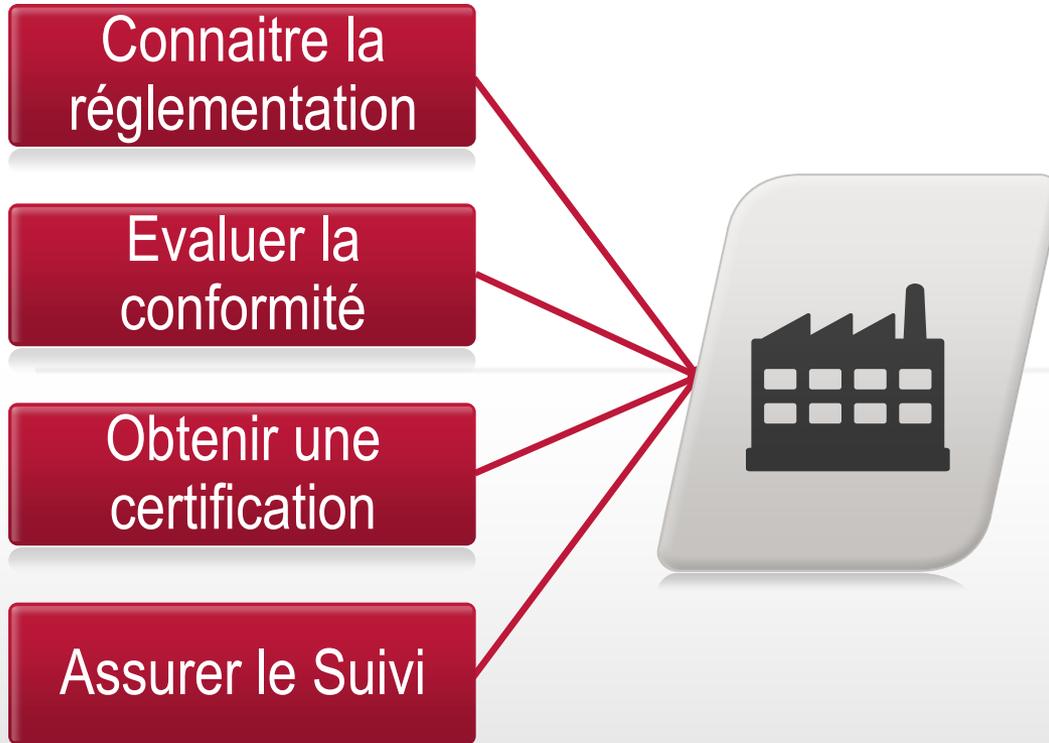


Accès aux marchés Europe et hors UE

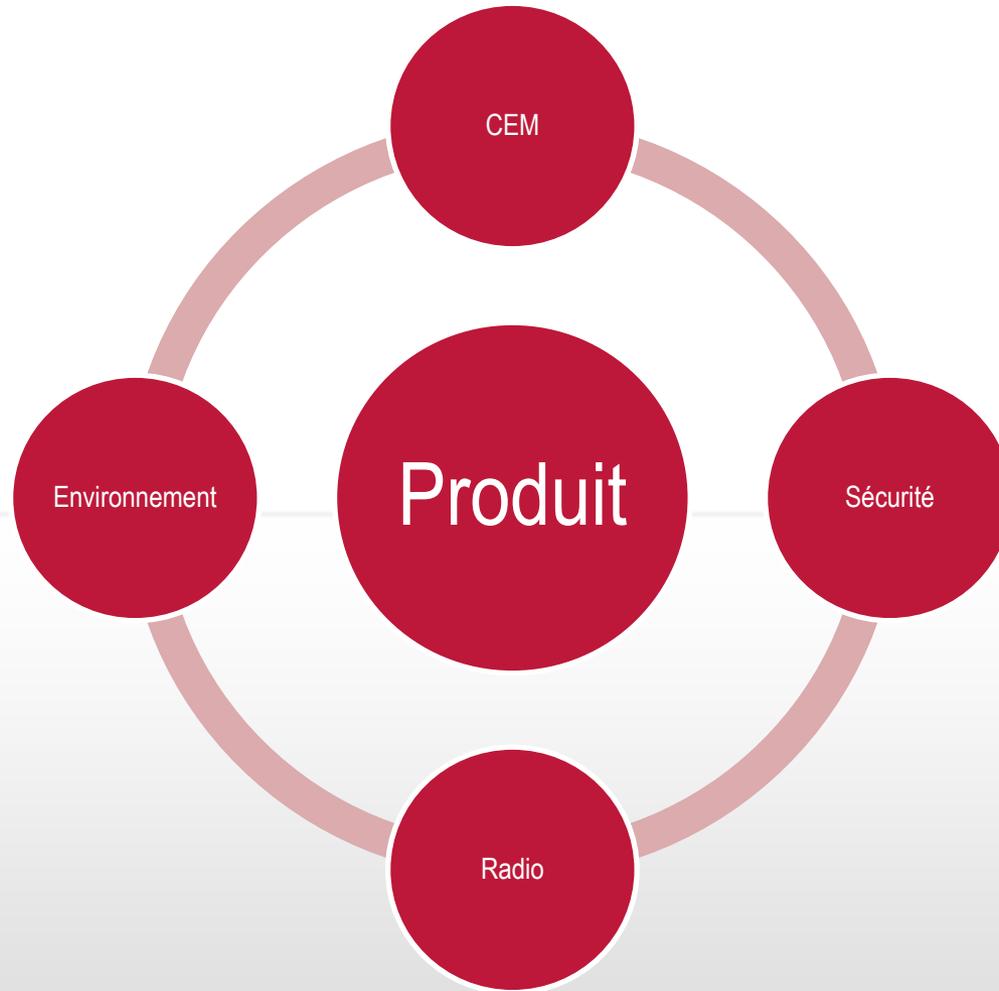
Eric WEIBEL – LCIE Pulversheim (68)

eric.weibel@lcie.fr





Identifier les réglementations applicables



Des réglementations variées, par zones mondiales



Europe : Essentiellement basé sur le Marquage CE

Secteurs de l'industrie

Grand public

Industrie

Médical

Télécommunication

Ferroviaire.



Marquage



Automobile

Cahier des charges

Marquage « e »

Aéronautique

Spatial

Militaire

Marine



Cahier des Charges
Marquage (défense)

► IECEE

- Organisme de la CEI chargé de la certification des équipements électriques, selon les normes éditées par la CEI (IEC en anglais).
- Secrétariat permanent à Genève qui anime:
 - Un Comité de Direction et de Certification (Certification and Management Committee: **CMC**).
 - Un Comité des Laboratoires d'essai (Committee of Testing Laboratories: **CTL**) regroupant les travaux d'interprétation de plusieurs groupes d'experts (Expert Task Force: **ETF**) des laboratoires d'essai membres.
 - Et un Comité d'Appel.





Le système OC – CB Scheme



- ▶ OC : Organisme de Certification (Certification Body: CB)
- ▶ MB: Member Body
 - Organisme de normalisation, d'un Etat Membre de l'IECEE, qui est membre du système OC.
- ▶ ONC: Organisme National de Certification (National Certification Body: NCB)
 - Un ONC peut être « Accepteur » ou « Emetteur et Accepteur ».
- ▶ CBTL: Certification Body Testing Laboratory
 - Laboratoire d'essai d'Organisme de Certification.
 - Un NCB peut avoir plusieurs CBTL.
 - Un CBTL peut appartenir à plusieurs NCB mais pas pour le même domaine de certification.
- ▶ TR: Test report
 - Rapport d'essai établi à partir d'un proforma appelé TRF.

Le système OC – CB Scheme

Objectif

► Système OC (CB Scheme) :

- Reconnaissance des essais réalisés selon les normes CEI (+ déviations) pour accéder aux marchés et/ou aux marques de certifications VIA un passeport qu'est le rapport et le certificat « OC »

Page 1 of 21

TEST REPORT
IEC 60 250

Safety of Information on technology equipment

Report reference No.
Issued by (printed name and signature)

Approved by (printed name and signature)

Date of issue

This report is based on a blank test report that was prepared by I RRO using information obtained from the TFS originate (see below).

Testing Label only Name

Address

Testing location

Applicant's Name

Address

Test specification

Standards .. IEC 60 250, 9th Edition (1999)

Test procedure .. CB-scheme

Procedure deviation

Non-standard test method

Test Report Form

Test Report Form No. 020_1 103-03

TFS originate .. I RRO

Model TFS .. dated 03-02

Copy right reserved to the bodies participating in the IECSE Schemes (CB and CB+CB) and to the bodies participating in the C.I.C (CC-CENELEC).

Test item description

Trademark

Model and its type reference

Rating(s)



IECEE
CB Scheme

Ref. Certif. No.

IEC SYSTEM FOR MUTUAL RECOGNITION SINCE TEST REPORTS FOR ELECTRICAL EQUIPMENT (IECSE) OF SCHEMES

SYSTEME D'ACCREDITATION MUTUELLE DE CERTIFICATS DES SERVICES D'ESSAIS POUR L'ELECTRIQUE (SCHEMAS) IECSE

CB TEST CERTIFICATE
CERTIFICAT D'ESSAI OC

Product
Produit

Numero scheme of the applicant
Numero scheme candidat

Numero scheme of the manufacturer
Numero scheme fabricant

Numero scheme of authority
Numero scheme autorite

Regulation applicable
Regulation applicable

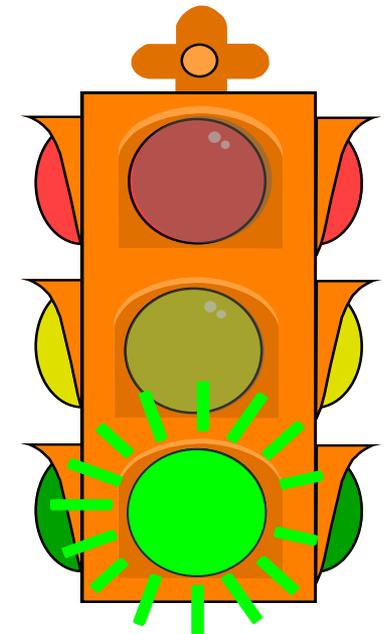
Technical file
Dossier technique

Head Type Rec
Régulateur

Declaration (Access to)
Déclaration (accès à)

Publication
Publication

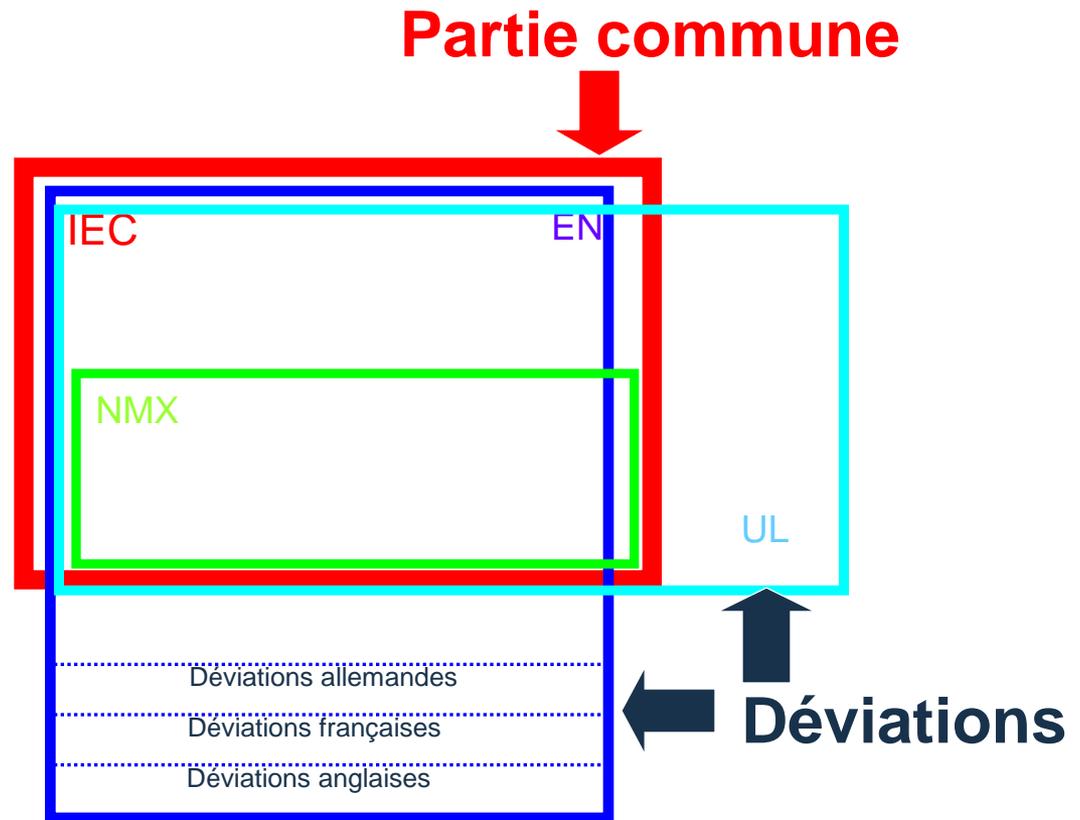
Signature
Signature



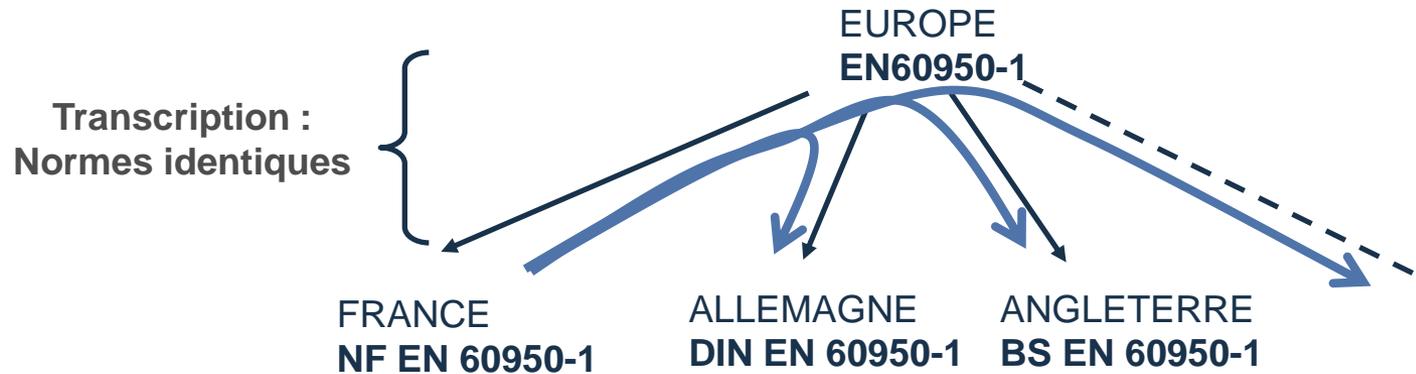
- ▶ Accord fondé sur la reconnaissance des seuls résultats d'essais effectués par les CBTL associés aux NCB membres du système OC.
- ▶ Plus de 45 pays sont membres de cet accord.
- ▶ Le Système OC (CB Scheme) permet:
 - l'accès direct à certains marchés internationaux (dont les pays ne sont pas nécessairement membres de la CEI ou de l'IECEE)
 - l'obtention de marques nationales dans les pays participant à l'accord

► Élimination des répétitions d'essais :

Référentiel pour la réalisation des essais sanctionnés dans le rapport et certificat OC.



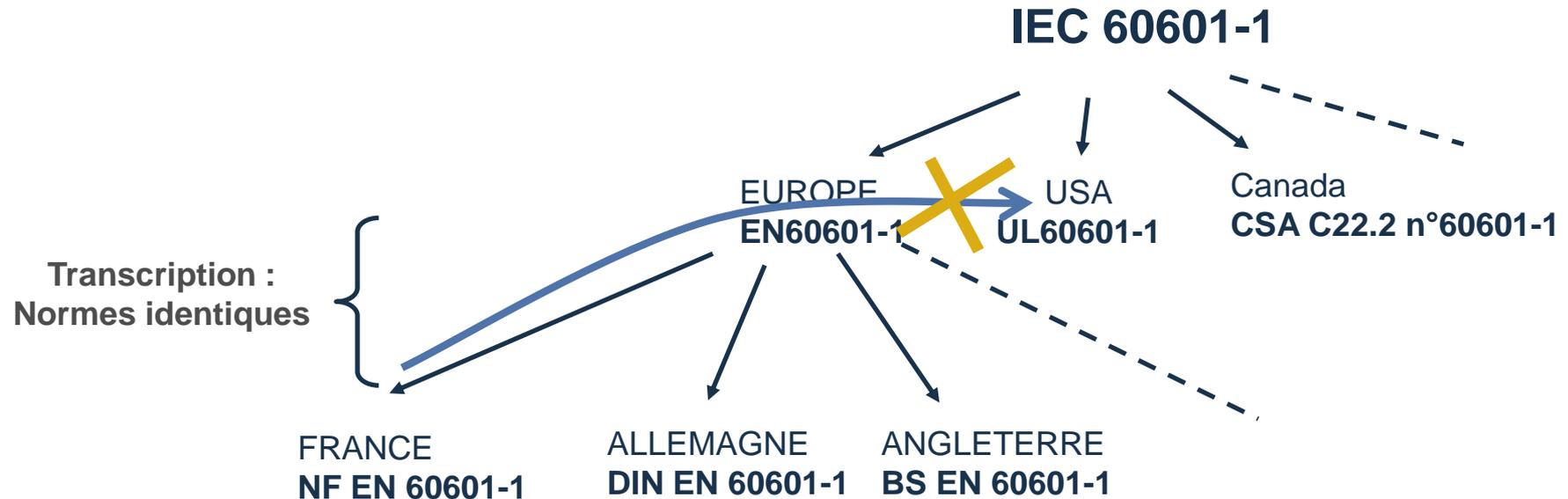
► Portée du rapport EN 60950-1



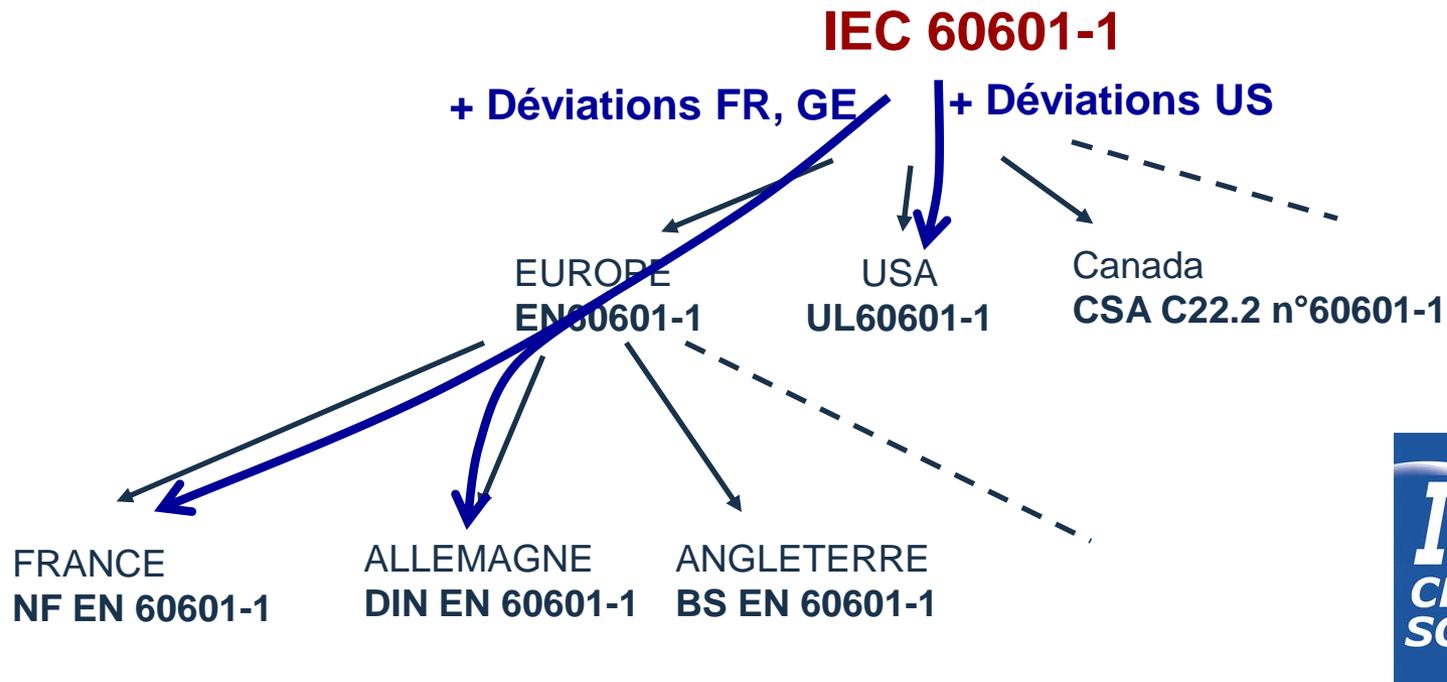
Le système OC – CB Scheme

Principe

- Un rapport EN 60950-1 n'est pas accepté au USA et au Canada car ne couvre pas leurs spécificités (déviations nationales).



- Un rapport CEI 60950-1 incluant les déviations nationales est accepté partout, même au USA et au Canada car il permet d'accéder aux normes nationales.



| Standard: | 60601-1(ed.2);am1;am2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|--|--------------------|----------------------|-------------------|---------------------|------------------|---------|-----------------------------|--|--------------------|-----------|-----------------|---|------------|--------|----------------------------|---|------------|---------|--------------|---|------------|--------|---------------|--|------------|--------|---------|---|------------|-------|------------------|---|------------|--------------------|------------------|---|------------|-----------|---------------|---|------------|----------|-----------------|--|------------|--------|--|--|------------|-------------|---|--|------------|-----|-----------|---|------------|
| Product category: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Title: | Medical electrical equipment - Part 1: General requirements for safety | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Year: | 1988-12-30 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  Click on the icon to open the associated document | |  FCS member | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| National differences | Group differences | Issuing/Recognizing | Recognizing only | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Country | National standard reference | | Last modification* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Australia | AS/NZS 3200-1-0 |  | 2007-05-29 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Canada | CAN/CSA 22.2 No. 601.1-M90 |  | 2007-05-29 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Denmark | not reported |  | 2007-05-29 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| France | NF EN 60601-1 | | 2011-01-31 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Israel | SI 1011 |  | 2010-05-26 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Japan | JIS T0601-1:1999 |  | 2009-08-19 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Korea, Republic Of | KS C IEC 60601-1 |  | 2010-08-02 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Singapore | SS 481 Part 1 |  | 2007-05-29 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Slovenia | SIST EN 60601-1 | | 2010-02-10 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Sweden | SS-EN 60601-1:1991 + T2:1995 + A2:1996 + A1:2001 | | 2010-06-03 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Switzerland | SN EN 60601-1:1990 + A2:95 + A11:93 + A12:93 + A13:96 |  | 2009-12-15 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Usa | UL 2601-1 |  | 2007-05-29 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Standard: | 60601-1(ed.3) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|--|---------------------------|-----------------------------|--------------------------|----------------------------|-------------------------|----------------|------------------------------------|--|---------------------------|--------|------------------------------|---|------------|--------|---------------|--|------------|-------|------------------|---|------------|--------------------|------------------|---|------------|----------|-----------------|--|------------|--------|---|--|------------|-------------|--------------------|---|------------|--------|--------------------|--|------------|----------------|--------------------|--|------------|-----|---------------------------|---|------------|
| Product category: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Title: | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Year: | 2005-12-15 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  Click on the icon to open the associated document | |  FCS member | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| National differences | Group differences | Issuing/Recognizing | Recognizing only | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Country | National standard reference | | Last modification* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| France | NF EN 60601-1 | | 2011-01-31 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Japan | JIS T0601-1:2012 |  | 2013-01-28 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Korea, Republic Of | KS C IEC 60601-1 |  | 2013-10-11 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Slovenia | SIST EN 60601-1 | | 2010-02-10 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Sweden | SS-EN 60601-1:2006+A11:2011+AC1:2014+A12:2014 | | 2014-12-05 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Switzerland | SN EN 60601-1:2006 |  | 2009-12-15 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Turkey | TS EN 60601-1:2009 | | 2014-04-24 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| United Kingdom | BS EN 60601-1:2006 |  | 2014-07-15 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Usa | ANSI/AAMI ES60601-1: 2005 |  | 2008-10-02 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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- ▶ Rapport d'essai (TR) et Certificat OC de type.
- ▶ Conformité de l'échantillon testé (à un instant donné).
- ▶ Reconnaissance de l'ensemble TR et Certificat par tous les autres membres du Système.
- ▶ Ne donne pas directement droit à l'apposition d'une marque, mais facilite la délivrance de certificat et de marques nationales dans les autres Etats Membres de l'IECEE.



Aspects radio

- 1) Des réglementations comme le marquage CE (Europe) basées sur une conformité aux exigences essentielles prévues par les Directives Européennes.
- 2) Procédure d'homologation locale :
 - a) Reconnaissances d'essais effectués par le LCIE dans de nombreux pays (Certification OC, Accords de reconnaissances, ...).
 - b) Essais locaux obligatoires : essais selon normes Européennes ou nord américaines pour la plupart des marchés, ou équivalentes.
 - c) Des réglementations locales importantes : nécessité de représentants locaux, à vérifier.

Exemples de pays

[Brésil](#)

Approbation des produits au Brésil.

| | |
|--|-------------------------|
| Sécurité électrique Obligatoire | La plupart des produits |
| CEM Obligatoire | Oui |
| Radio Obligatoire | Oui |
| Télécommunication Obligatoire | Oui |
| Essais imposés localement | Oui |
| Représentant local requis | Oui |

[Oman](#)

Approbation des produits à Oman

| | |
|--|------------|
| Sécurité électrique Obligatoire | Non |
| CEM Obligatoire | Non |
| Radio Obligatoire | Oui |
| Télécommunication Obligatoire | Oui |
| Essais imposés localement | Non |
| Représentant local requis | Non |

[Etats-Unis d'Amérique / Canada](#)

Approbation des produits aux Etats-Unis/Canada

| | USA | Canada |
|--|-----|--------|
| Sécurité électrique Obligatoire | Oui | Oui |
| CEM Obligatoire | Oui | Oui |
| Radio Obligatoire | Oui | Oui |
| Télécommunication Obligatoire | Oui | Oui |
| Essais imposés localement | Non | Non |
| Représentant local requis | Non | Oui |

- Source : www.lcie.fr

LCIE Certification – Agréments selon pays

► Bilateral agreements

- Argentina : BV, IRAM
- Australia : SAI Global
- Belarus : BELLIS
- Brazil : BV Brasil and TUV Rheinland do Brazil
- China : CQST, NEPSI/SIPAI, PCEC
- Germany : TUV PS, GS
- Japan : JET
- Korea : KTL
- Mexico : ANCE
- Norway : NEMKO
- Oman : TRAPoland : PREDOM-OBR, BBJ-SEP
- Russia : GOST
- Uruguay : UNIT
- USA : FM

► Recognitions

- Hong Kong : EMSD
- Japan : JET, TIIS
- Taiwan : BSMI

► Export control

- Iraq: COSQC
- Iraq: KSQCA (Kurdistan)
- Iran : ISIRI
- Lebanon : IRI
- Kuwait : PAI
- Saudi Arabia : MOCI-SASO
- Ghana: GSA
- Kenya: KEBS
- Tanzania: TBS
- Uganda: UNBS
- Ethiopia: MOTI

► Accreditation

- USA : FCC

► Specific agreement

- Malaysia : SIRIM International

Reconnaissances Bureau Veritas



ISO 17025
ISO Guide 65



RCB



CBTL



TCB



The Wireless Association*

CATL



FCB



WFDCL, WFDVL, WCB



UKAS



American National
Standards Institute



Standards Council of Canada
Conseil canadien des normes





BUREAU
VERITAS

Move Forward with Confidence*