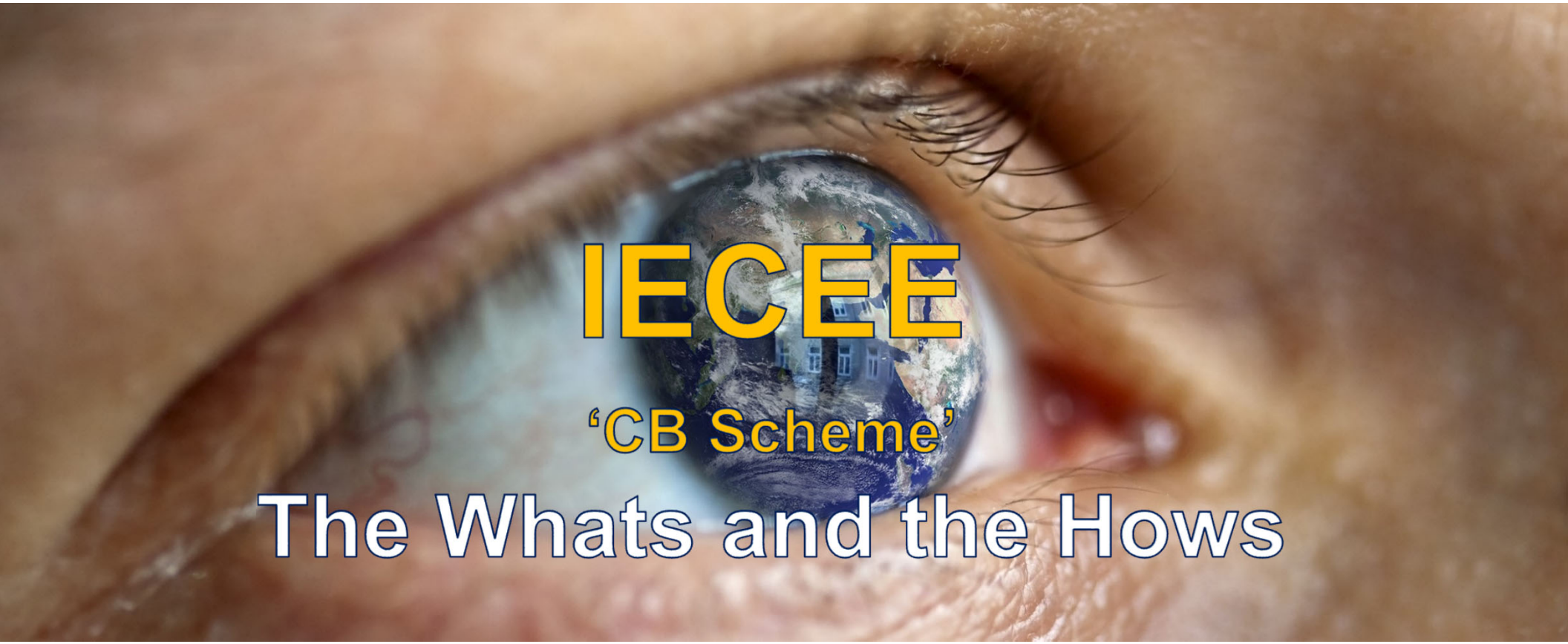



**Utilization of Voluntary Consensus Standards and Conformity Assessment**

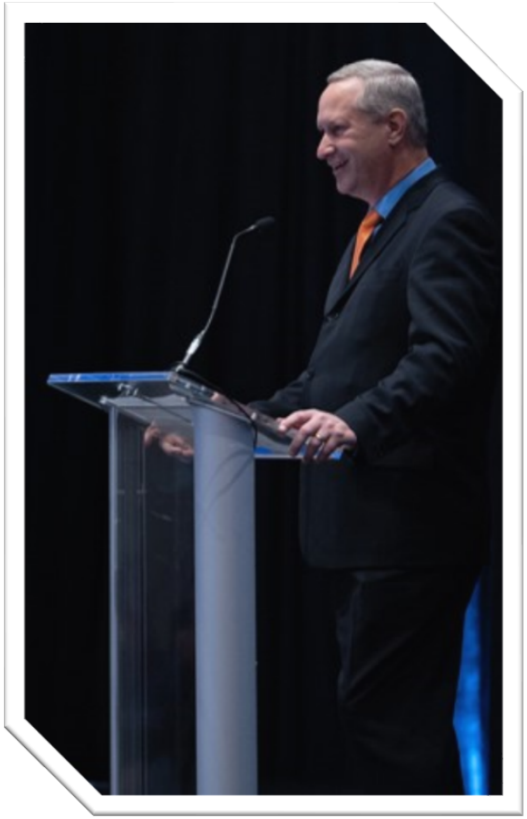
Case Study: IECEE 2023-11 (Steven Margis)

Medical Device Regulatory Convergence Project (MDRC): Kenya

IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components

# Steven Margis

Steven.T.Margis@ul.com

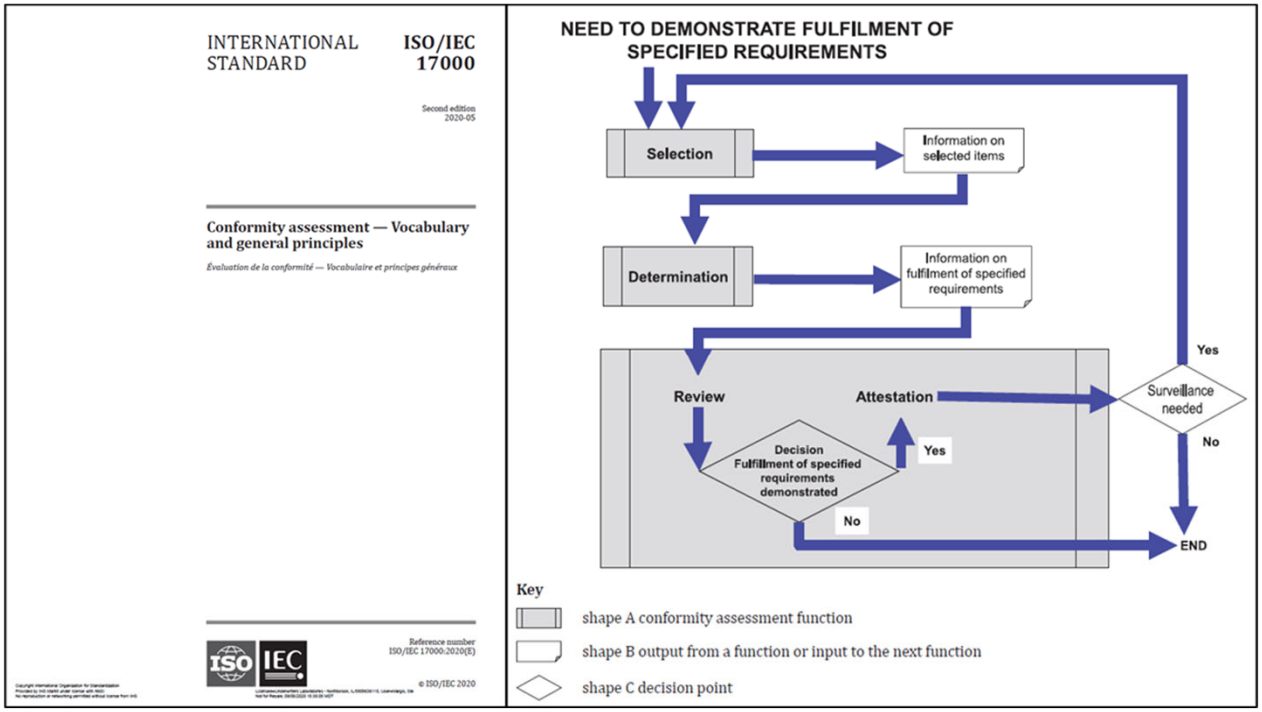


- IECEE Chair (2022-Present)
  - Vice Chair (2019-2021)
- Incoming IEC Vice President and Chair, Conformity Assessment Board (CAB) (2024 - )
  - CAB member (2014-2019, 2022-Present)

- Director, Conformity Assessment Programs

# Conformity Assessment

"demonstration that **specified requirements** are fulfilled"



# Specified Requirements

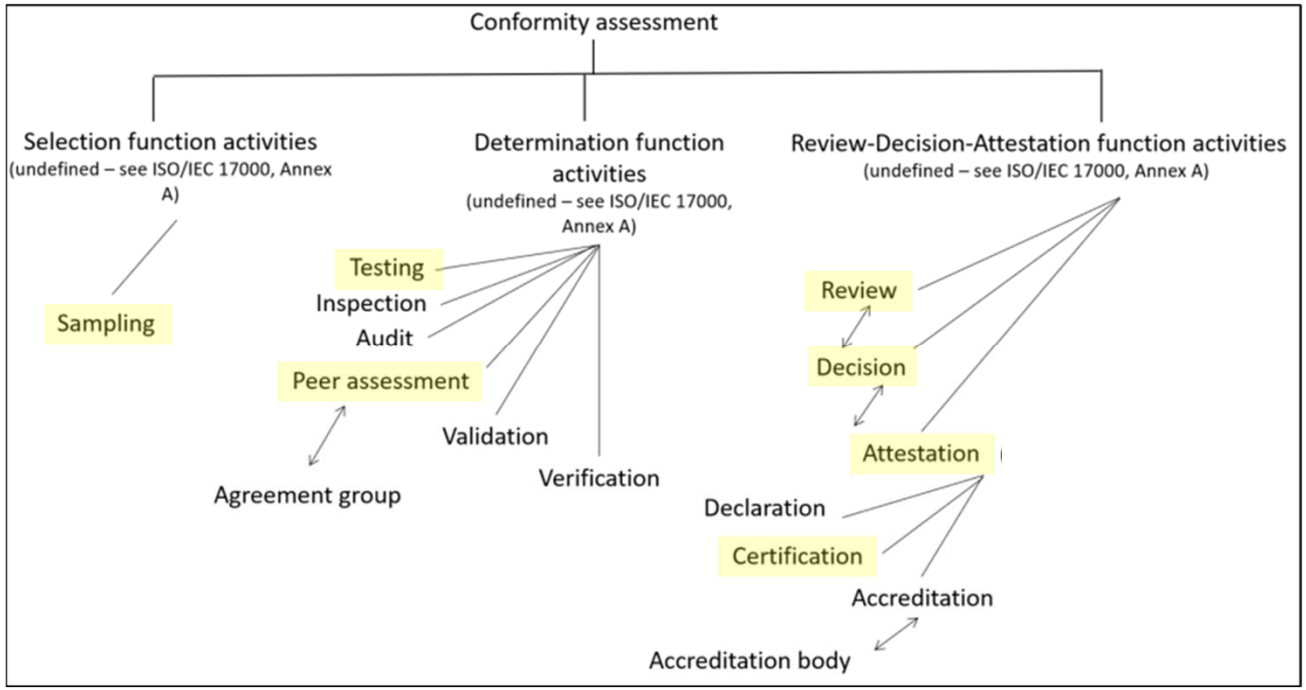
Conformity Assessment

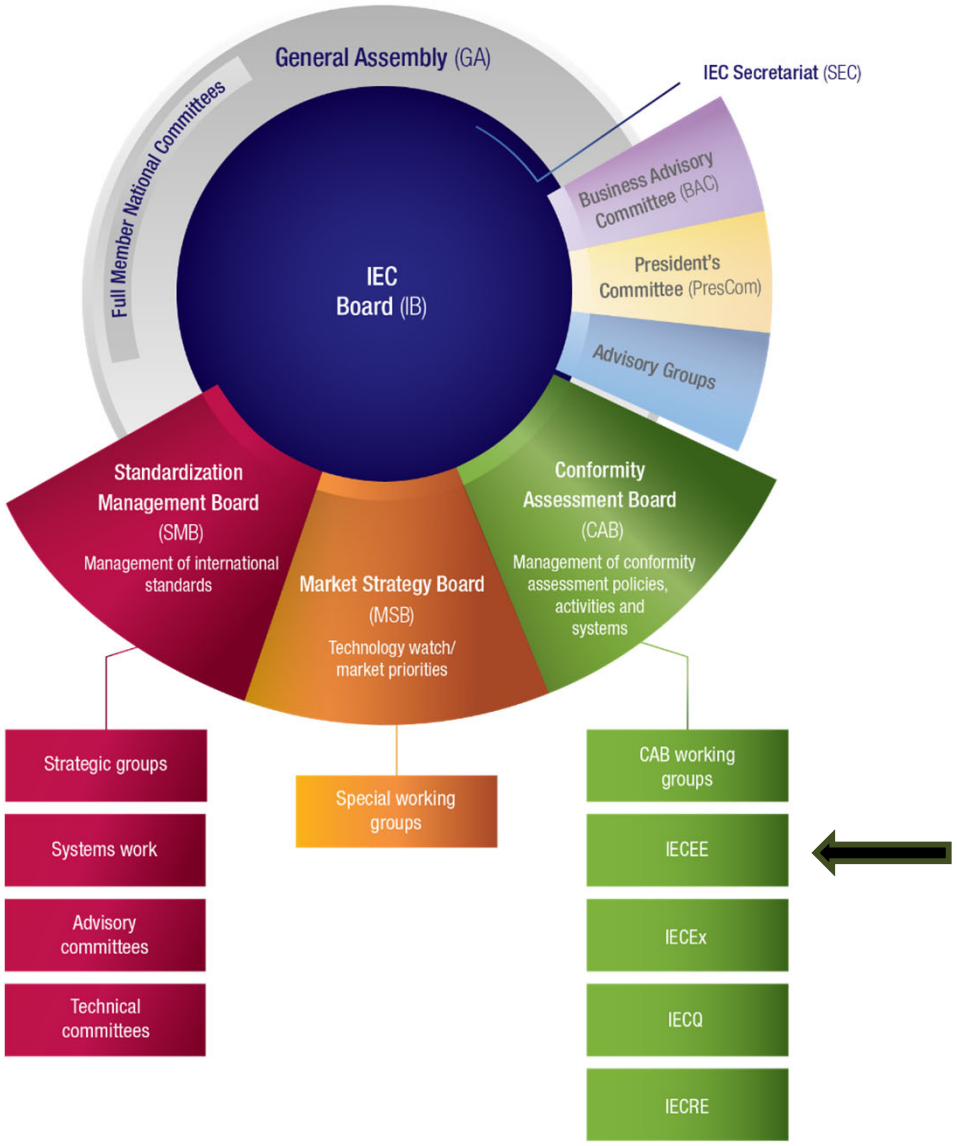
## “need or expectation that is stated”

*NOTE: Specified requirements may be stated in normative documents such as **regulations**, **standards** and **technical specifications**.*

# Conformity Assessment

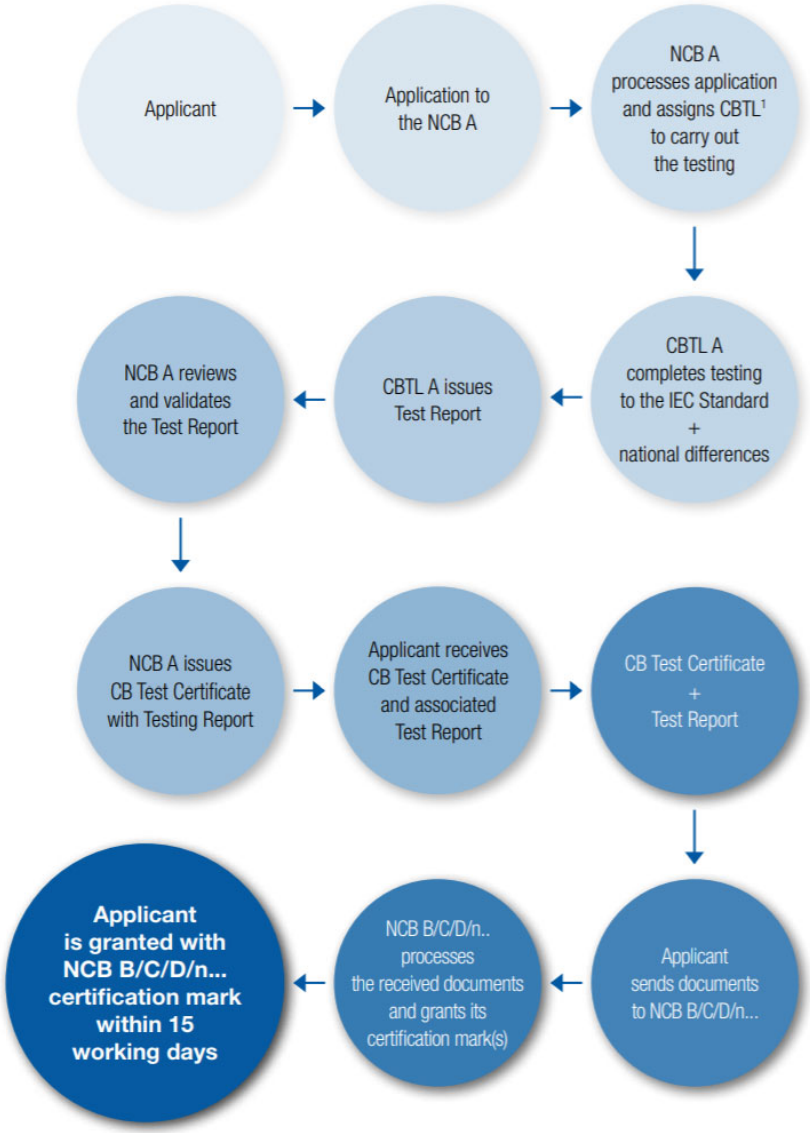
**Source: ISO Presentation on ISO/IEC 17000:2020**




General Assembly (GA)
Full Member National Committees
IEC Secretariat (SEC)
IEC Board (IB)
Business Advisory Committee (BAC)
President's Committee (PresCom)
Advisory Groups
Standardization Management Board (SMB)
Management of international standards
Market Strategy Board (MSB)
Technology watch/ market priorities
Conformity Assessment Board (CAB)
Management of conformity assessment policies, activities and systems
Strategic groups
Systems work
Advisory committees
Technical committees
Special working groups
CAB working groups
IECEE
IECEx
IECQ
IECRE

## IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components

- **Facilitate trade** by eliminating duplication of testing and providing market access
- National adoption and use of **IEC standards** (with or without differences)
- **Mutual acceptance** of IECEE certificates and their related test reports
- **Peer Assessment** to ensure competence, consistency and mutual confidence


Applicant
Application to the NCB A
NCB A processes application and assigns CBTL[1] to carry out the testing
CBTL A completes testing to the IEC Standard + national differences
CBTL A issues Test Report
NCB A reviews and validates the Test Report
NCB A issues CB Test Certificate with Testing Report
Applicant receives CB Test Certificate and associated Test Report
CB Test Certificate + Test Report
Applicant sends documents to NCB B/C/D/n...
NCB B/C/D/n.. processes the received documents and grants its certification mark(s)
Applicant is granted with NCB B/C/D/n... certification mark within 15 working days


Argentina


Australia


Austria


Bahrain


Belarus


Belgium


Brazil


Bulgaria


Canada


Chile


China


Colombia


Croatia


Czech Republic


Denmark


Finland


France


Germany


Greece


Hungary


India


Indonesia


Israel


Italy


Japan


Kenya


Korea, Rep. Of


Malaysia


Mexico


Netherlands


New Zealand


Nigeria


Norway


Pakistan


Poland


Portugal


Russian Federation


Saudi Arabia


Serbia, Rep. Of


Singapore


Slovakia


Slovenia


South Africa


Spain


Sweden


Switzerland


Thailand


Turkey


Ukraine


United Arab Emirates

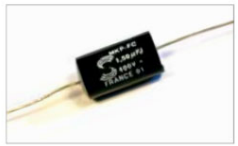

United Kingdom


US


Vietnam

**BATT**
Batteries

**CABL**
Cables and cords

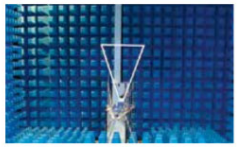


**CAP**
Capacitors as components


**CONT**
Switches for appliances and automatic controls for electrical household appliances


**E3**
Electrical energy efficiency

**ELVH**
Electrical vehicles



**EMC**
Electromagnetic compatibility

**HOUS**
Household and similar equipment

**INDA**
Industrial automation

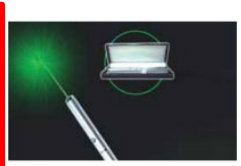
**INST**
Installation accessories & connection devices

**ITAV**
Information technology audio video

**LITE**
Luminaires

**MEAS**
Measuring instruments

**MED**
Electrical equipment for medical use



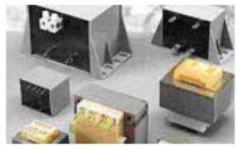
**MISC**
Miscellaneous

**OFF**
IT and office equipment

**POW**
Low voltage, high power switching equipment

**PROT**
Installation protective equipment

**PV**
Photovoltaics

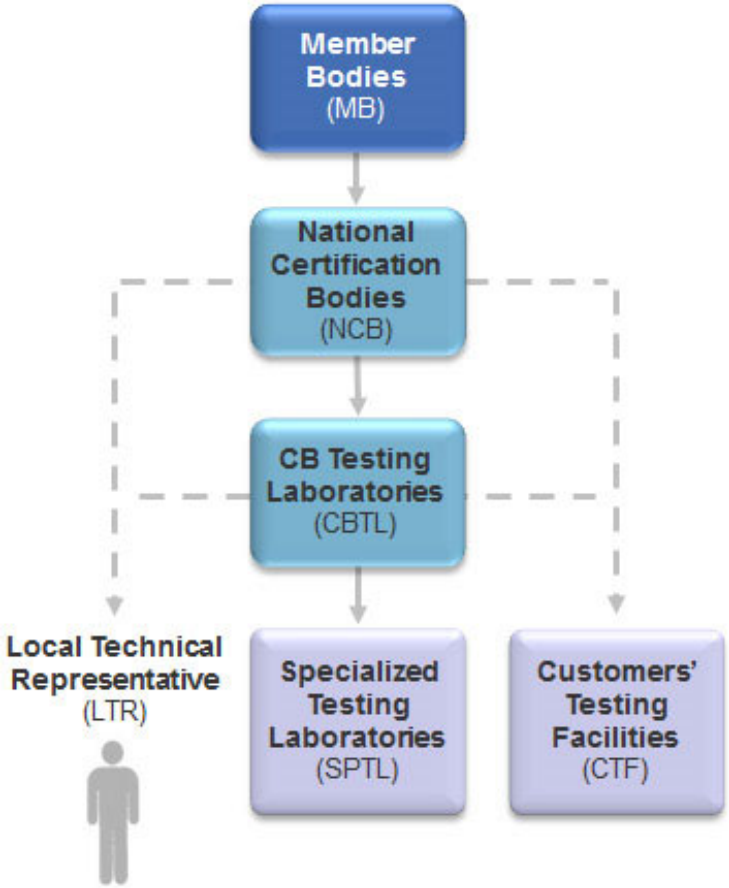


**SAFE**
Safety transformers and similar equipment

**TOOL**
Portable tools

**TRON**
Electronics, entertainment

- 54 Member Bodies
- 93 Certification Bodies
- 583 Testing Laboratories
- 2046 Customer Testing Facilities
- 120,000+ Certificates (2022)
  - Over 1.7M Issued
- **MED**
  - 28 Member Bodies
  - 50 Certification Bodies
  - 159 Testing Laboratories
  - 291 Standards
  - 2.7% of all Certificates: 2022 (3221)



# MED: NCB Economies

| | | |
|---|---|---|
| *Belgium** | *Hungary** | Singapore |
| Belarus (R) | Israel | *Slovenia** |
| Canada | *Italy** | *Spain** |
| China (R) | Japan | *Sweden** |
| *Czech Republic** | Republic of Korea | Switzerland^ |
| *Denmark** | *Netherlands** | Turkey (R) |
| *Finland** | *Norway*** | Ukraine |
| *France** | *Poland (R)** | United Kingdom |
| *Germany** | *Portugal (R)** | United States |

Key: R: Recognizing Only; ^: Observer; IMDRF Member Countries (*EU**, *EEA***)

*[IMDRF Members Not Participating: Argentina^, Australia, Brazil, Russian Federation]*

# MED


IEC 60601-1

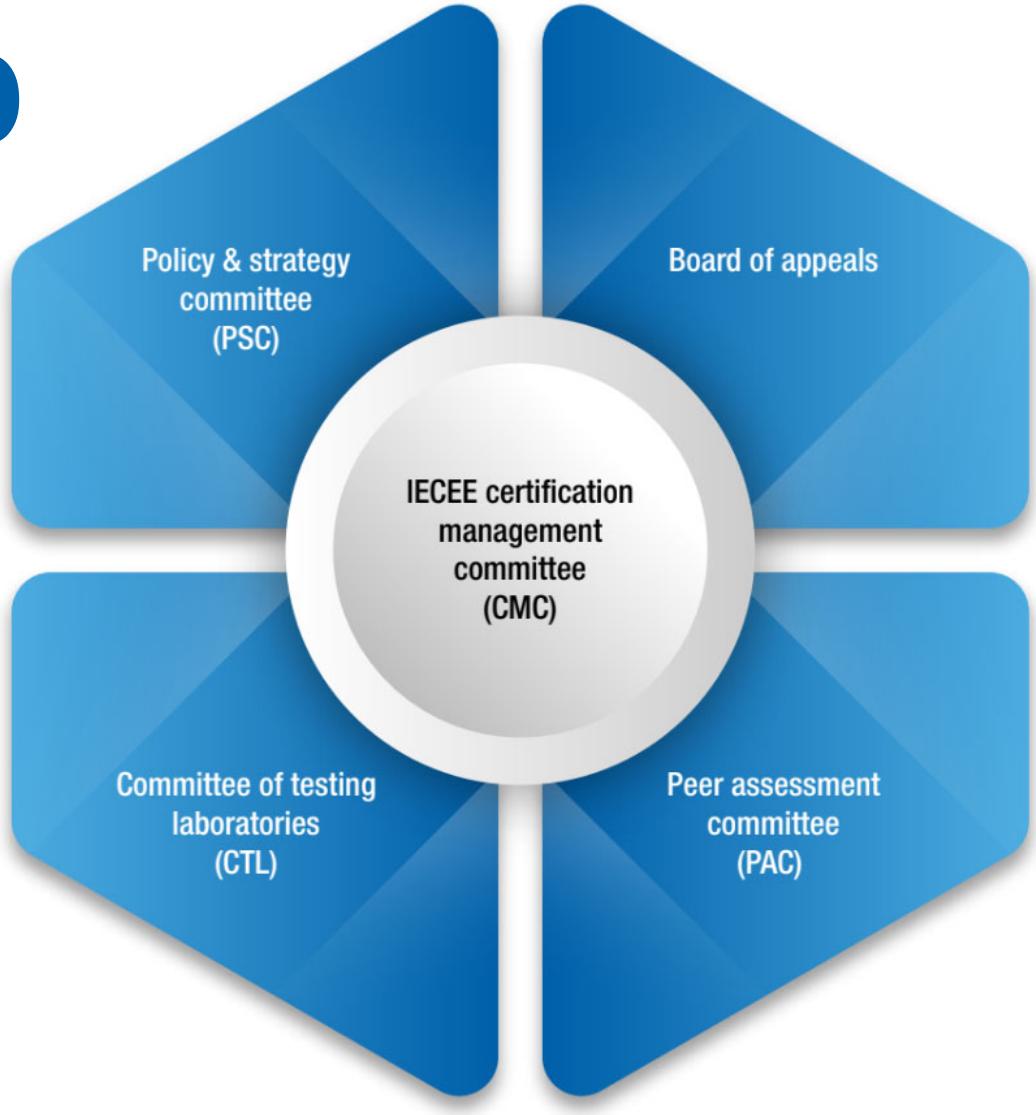
INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance

Appareils électromédicaux –
Partie 1: Exigences générales pour la sécurité de base et les performances essentielles

**Editions:**
1988 & 2005



# MED

IECEE OD-2044

## IECEE
## OPERATIONAL DOCUMENT

IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE System)

Committee of Testing Laboratories (CTL)

Evaluation of Risk Management in medical electrical equipment according to the IEC 60601-1 & ISO/IEC 80601-1 Series of Standards

IECEE OD-2044:2019(EN)

IECEE OD-2055

## IECEE
## OPERATIONAL DOCUMENT

IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE System)

Guideline Document on Medical Electrical Equipment in the CB Scheme according to the IEC 60601 and IEC/ISO 80601 Series of Standards

IECEE OD-2055:2017(en)

### CTL DECISION SHEET (DSH)

| Standard(s) (incl. year) | Subclause(s) | Tracking No. | Year |
|---|---|---|---|
| IEC 60601-1: 2005 (ed 3 .0) | 8.9 | 2017 | 2015 |
| **Category** | | | |
| MED | | | |
| **Subject** | **Keywords** | **Developed by** | **Approved at** |
| Creepage distance | Creepage distance<br>Working voltage, PCB traces | ETF-3 | 2016 CTL Plenary Meeting |

**Question**

How should the creepage distance be measured in a scenario where the point with the highest working voltage is behind a point with a lower working voltage?

See the case study below for details:

Creepage distance requirement on a Class II switch mode power supply unit designed for 2 MOPP.

A working voltage of 240 Vrms was measured between the secondary side and the nearest printed track on the primary side.

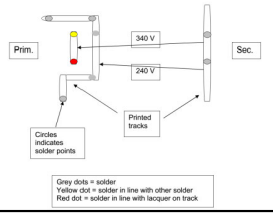
However, behind the nearest printed track on the primary side there is a point with a working voltage of 340 Vrms.

The creepage distance between secondary and the nearest 240 V point is 8 mm, which meets the requirement for 240 V.

The creepage distance between the 340 V point and the 240 V point is 1 mm.

Question:

How shall the creepage distance between primary and secondary be measured in such a case?




### TESTING AND MEASURING EQUIPMENT/ALLOWED SUBCONTRACTING
### IEC 60601-1:2005 + Am.1:2012
### Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

"R" Required
"S" May be subcontracted, see OD 2012
"SPTL" Specialized Facility, see IECEE 02-2
"W" Witness testing in the categories "MED" and "MEAS"
"3PPS" Three Phase Power Supply required

| Clause | Measurement/testing | Testing / measuring equipment / material needed | Subcontracting |
|---|---|---|---|
| 4.11 | Power input | Suitable devices for the voltage, current/power and frequency<br>Supply: 1 phase and 3 phase variacs | R |
| 5.3 | Ambient temperature, humidity, atmospheric pressure | Suitable devices for recording ambient temperature, humidity, atmospheric pressure | R |
| 5.7 | Humidity preconditioning treatment | Environmental conditions: Climate chamber controlling temperature and humidity | R |
| 5.9.2 | Accessible parts | Force gauge (30 N), standard test finger (figure 6), | R |

# MED

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

Ref. Certif. No.

**CB TEST CERTIFICATE**

Product

Name and address of the applicant

Name and address of the manufacturer

Name and address of the factory

*Note: When more than one factory, please report on page 2*

☐ Additional Information on page 2

Ratings and principal characteristics

Trademark / Brand (if any)

Customer's Testing Facility (CTF) Stage used

Model / Type Ref.

Additional information (if necessary may also be reported on page 2)

☐ Additional Information on page 2

A sample of the product was tested and found to be in conformity with

As shown in the Test Report Ref. No. which forms part of this Certificate

This CB Test Certificate is issued by the National Certification Body

Date: Signature:

**Test Report issued under the responsibility of:**

**IEC 60601-1**
**Medical electrical equipment**
**Part 1: General requirements for basic safety and essential performance**

**Report Reference No.**.....:
**Date of issue** .....:
**Total number of pages**.....:

**CB Testing Laboratory**.....:
**Address** .....:

**Applicant's name**.....:
**Address** .....:

**Test specification:**
**Standard**.....: IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012
(or IEC 60601-1:2012 reprint)

**Test procedure**.....: CB Scheme
**Non-standard test method**.....:

**Test Report Form No.**.....: IEC60601_1N
**Test Report Form Originator**.....: UL(US)
**Master TRF** .....: 2019-09-17



If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

**This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.**

**General disclaimer:**

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

| | | | |
|---|---|---|---|
| 4 | GENERAL REQUIREMENTS | | |
| 4.1 | Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse | | |
| 4.2 | RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS | | |
| 4.2.2 | General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2007).....: | See Appended RM Results Table 4.2.2. | |
| 4.2.3 | Evaluating RISK | | |
| 4.2.3.1 | a) Compliance with the standard reduces residual risk to an acceptable level | | |
| | b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN.....: | RISK MANAGEMENT PLAN Document: __ | |
| | c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists. | | |
| | - HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS. | | |
| 4.2.3.2 | MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series. | | |
| 4.3 | Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS. | RM File Reference to Essential performance: __ | |
| | - Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION. | | |
| | - Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated | | |
| | - Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE ..... : | See Appended Table 4.3 | |
| | - RISK CONTROL measures implemented | | |
| | - Methods used to verify the effectiveness of RISK CONTROL measures implemented | | |
| 4.4 | EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE .....: | | |
| 4.5 | Alternative RISK CONTROL methods utilized: | | |

# Other Considerations

- Cybersecurity
  - IEC 62443, ETSI 303 645
- *Functional Safety*
  - IEC 61508
- *Personnel Competence*

# A Methodical Approach

## … to Medical Device Regulation

- Participate
- Object of Conformity Assessment
- Specified Requirements
- Conformity Assessment Activity
- Conformity Assessment System / Scheme
- Global Optimization


IEC
IECEE
TM

IMDRF International Medical Device Regulators Forum

- Australia Therapeutic Goods Administration
- Brazil National Health Surveillance Agency (ANVISA)
- Canada Health Canada
- China China Food and Drug Administration
- European Union European Commission Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
- Japan Pharmaceuticals and Medical Devices Agency and the Ministry of Health, Labour and Welfare
- Russia Russian Minstry of Health
- Singapore Health Sciences Authority
- South Korea Ministry of Food and Drug Safety
- United Kingdom Medicines and Healthcare products Regulatory Agency
- United States of America US Food and Drug Administration

*Note: Regional Harmonization Initiative (Africa) African Medical Devices Forum (AMDF)*



IEC IECEE