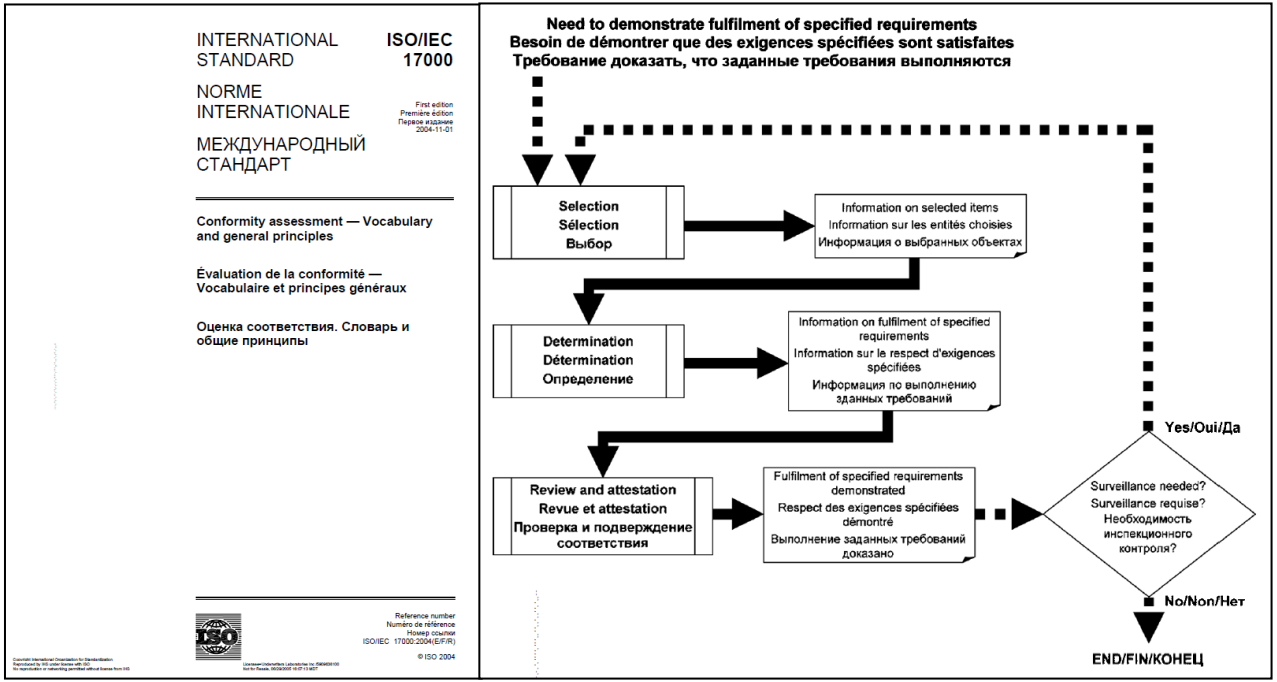
Steven Margis
Director: EIECEE
Director de UL, Programa de Evaluación de la Conformidad

Utilización de normas voluntarias de consenso y evaluación de la conformidad
17-03-2022
Seminario Web sobre Dispositivos Médicos – Sesión IV

International Electrotechnical Commission

Evaluación de la Conformidad

“demostración de que se cumplen los **requisitos especificados** relativos a un producto, proceso, sistema, persona u organismo”



Requisitos Especificados

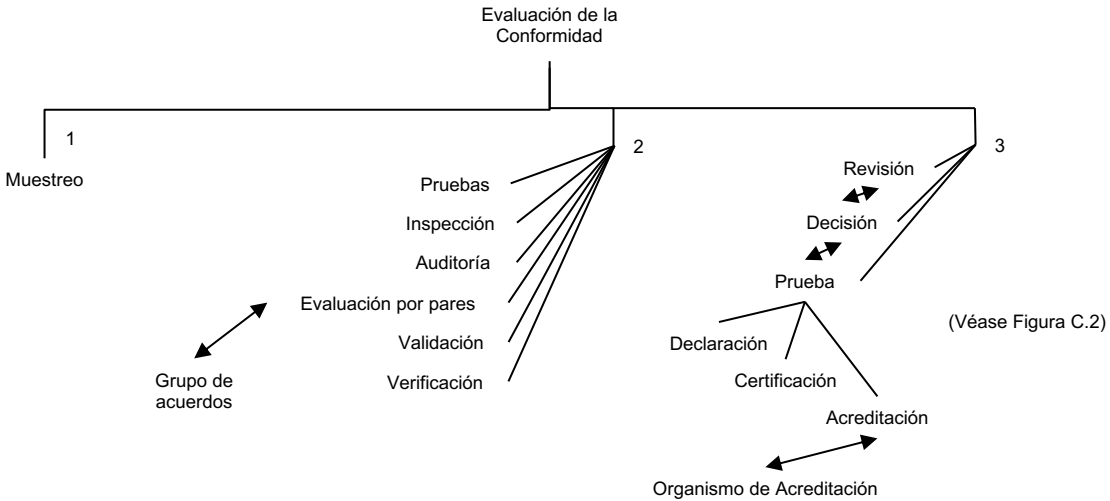
Evaluación de la Conformidad

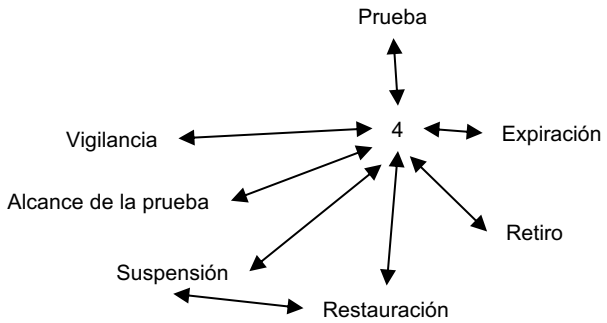
“necesidad o expectativa que se declara”

*NOTA: Los requisitos especificados pueden indicarse en documentos normativos tales como **regulaciones**, **normas** y **especificaciones técnicas***

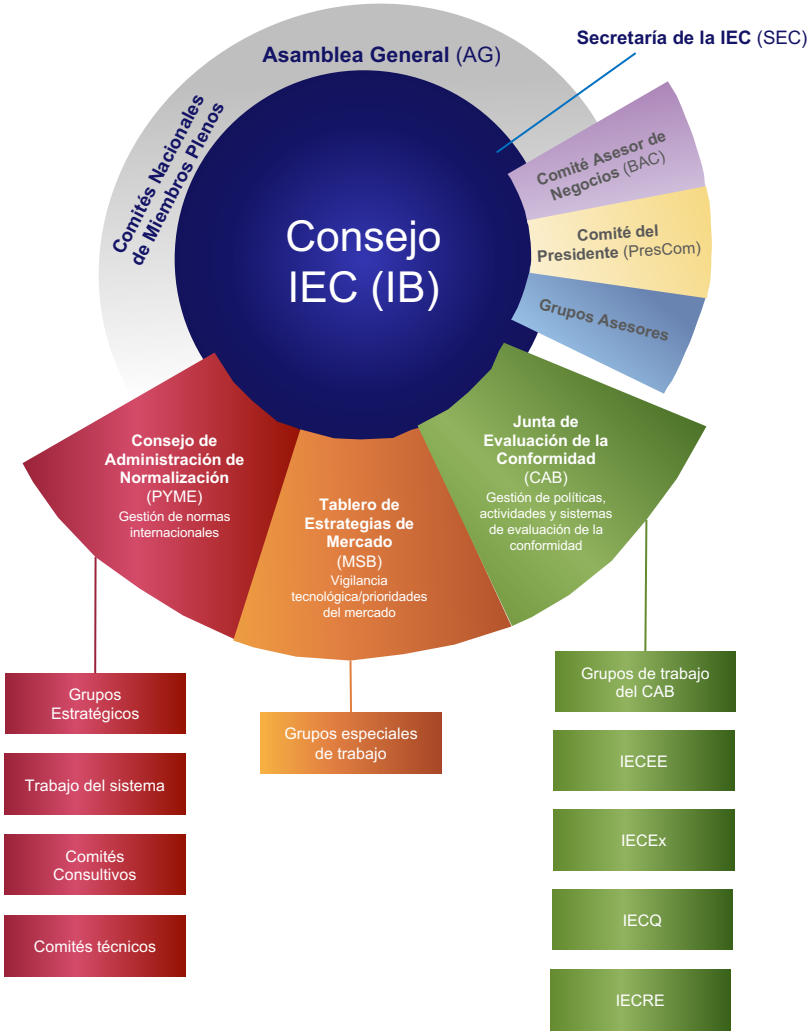
Evaluación de la Conformidad

"demostración de que se cumplen los **requisitos especificados**"



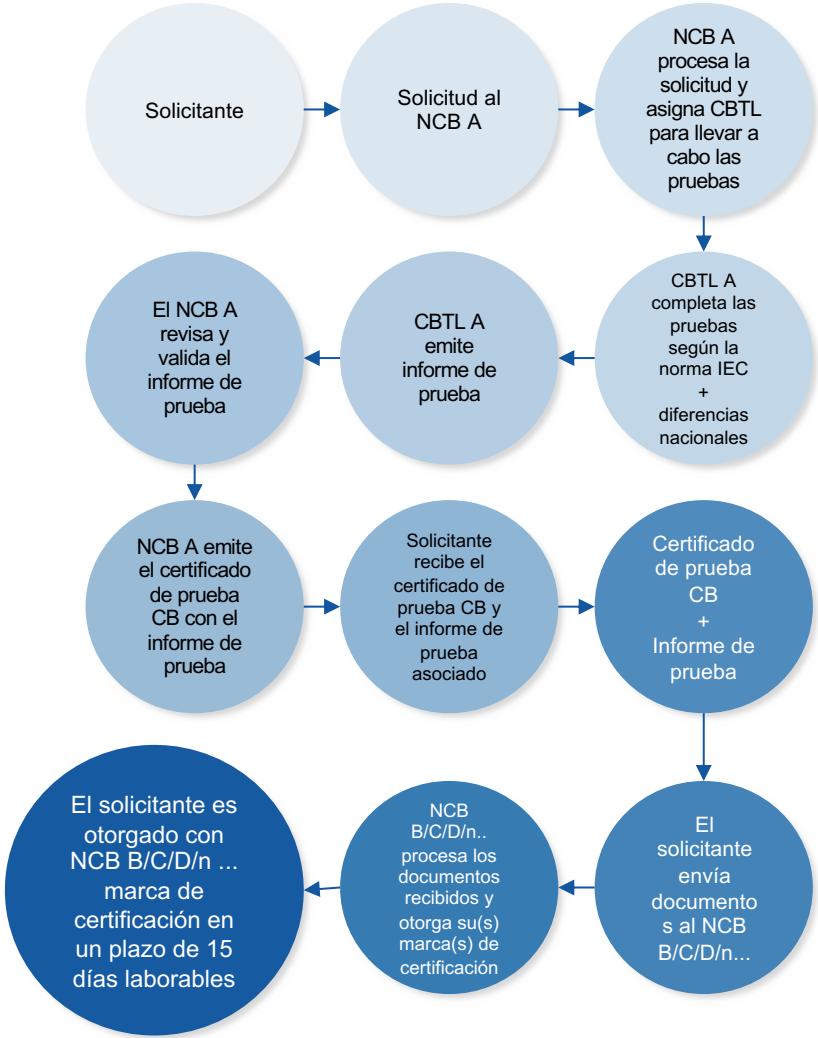


Fuente: ISO con respecto a ISO/IEC 17000: 2019


Asamblea General (AG)
Secretaría de la IEC (SEC)
Comités Nacionales de Miembros Plenos
Consejo IEC (IB)
Comité Asesor de Negocios (BAC)
Comité del Presidente (PresCom)
Grupos Asesores
Consejo de Administración de Normalización (PYME)
Gestión de normas internacionales
Tablero de Estrategias de Mercado (MSB)
Vigilancia tecnológica/prioridades del mercado
Junta de Evaluación de la Conformidad (CAB)
Gestión de políticas, actividades y sistemas de evaluación de la conformidad
Grupos Estratégicos
Trabajo del sistema
Comités Consultivos
Comités técnicos
Grupos especiales de trabajo
Grupos de trabajo del CAB
IECEE
IECEx
IECQ
IECRE

Sistema IEC de Esquemas de Evaluación de la Conformidad para Equipos y Componentes Electrotécnicos

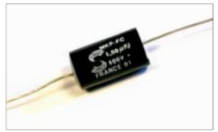
- **Facilitar el comercio** eliminando la duplicación de pruebas y proporcionando acceso a los mercados
- Adopción y uso nacional de las **normas IEC** (con o sin diferencias)
- **Aceptación mutua** de los certificados EIECEE y sus informes de ensayo relacionados
- **Evaluación por pares** para garantizar la competencia, la coherencia y la confianza mutua


Solicitante
Solicitud al NCB A
NCB A procesa la solicitud y asigna CBTL para llevar a cabo las pruebas
CBTL A completa las pruebas según la norma IEC + diferencias nacionales
CBTL A emite informe de prueba
El NCB A revisa y valida el informe de prueba
NCB A emite el certificado de prueba CB con el informe de prueba
Solicitante recibe el certificado de prueba CB y el informe de prueba asociado
Certificado de prueba CB + Informe de prueba
El solicitante envía documento s al NCB B/C/D/n...
NCB B/C/D/n.. procesa los documentos recibidos y otorga su(s) marca(s) de certificación
El solicitante es otorgado con NCB B/C/D/n ... marca de certificación en un plazo de 15 días laborables

- Argentina
- Australia
- Austria
- Bahréin
- Bielorrusia
- Bélgica
- Brasil
- Bulgaria
- Canadá
- Chile
- China
- Colombia
- Croacia
- República Checa
- Dinamarca
- Finlandia
- Francia
- Alemania
- Grecia
- Hungría
- India
- Indonesia
- Israel
- Italia
- Japón
- Kenia
- República de Corea
- Malasia
- México
- Holanda
- Nueva Zelanda
- Nigeria
- Noruega
- Pakistán
- Polonia
- Portugal
- Federación Rusa
- Arabia Saudita
- República de Serbia
- Singapur
- Eslovaquia
- Eslovenia
- Sudáfrica
- España
- Suecia
- Suiza
- Tailandia
- Turquía
- Ucrania
- Emiratos Árabes Unidos
- Reino Unido
- Estados Unidos
- Vietnam

BATT
Batteries

CABL
Cables and cords

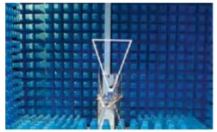


CAP
Capacitors as components

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

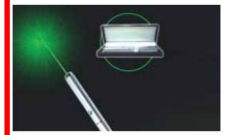
INST
Installation accessories & connection devices

ITAV
Information technology audio video

LITE
Luminaires

MEAS
Measuring instruments

MED
Electrical equipment for medical use



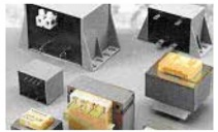
MISC
Miscellaneous

OFF
IT and office equipment

POW
Low voltage, high power switching equipment

PROT
Installation protective equipment

PV
Photovoltaics

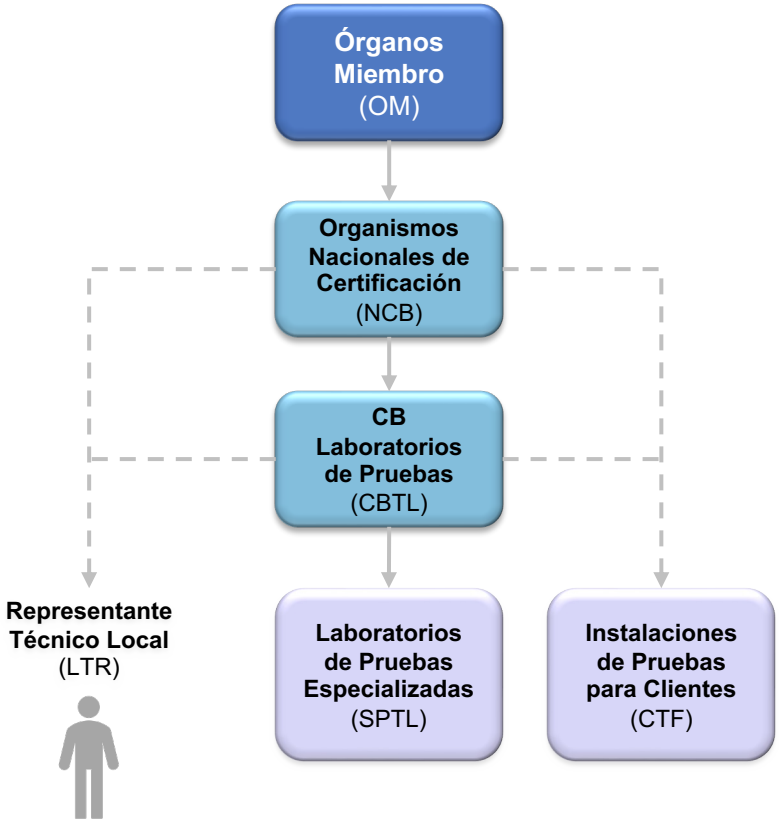


SAFE
Safety transformers and similar equipment

TOOL
Portable tools

TRON
Electronics, entertainment

- 54 Órganos Miembro
- 91 Organismos de Certificación
- 556 Laboratorios de Pruebas
- 1794 Instalaciones de Pruebas para Clientes
- Más de 120.000 certificados (2020)
  - Más de 1.5 millones emitidos
- **MED**
  - 28 Órganos Miembro
  - 51 Organismos de Certificación
  - 148 Laboratorios de Pruebas
  - 275 Normas
  - 2.8% de todos los certificados (3503)



MED: Economías de los NCB

*Bélgica**
Bielorrusia (R*)
Canadá
*República Checa**
*Dinamarca**
*Finlandia**
*Francia**
*Alemania**
*Hungría**

Israel
*Italia**
Japón
República de Corea
*Holanda**
*Noruega***
Polonia (R*)
Portugal (R*)
Serbia (R)

Singapur
*Eslovaquia**
*Eslovenia**
*España**
*Suecia**
Suiza**
Turquía (R*)
Ucrania
Reino Unido
Estados Unidos

Key: Países Miembro de IMDRF (*EU**, *EEA***) R: Solo Reconocer

[no participan Australia, Austria, Brasil, China, Federación Rusa]

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

Ediciones:
1998 & 2005

MED

IECEE OD-2044

Edition 2.3 2019-06

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

Edition 2.1 2017-05-17

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 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.

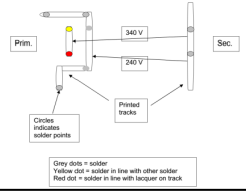
However, behind the nearest printed track on the primary side there is a point with a working voltage of 340 Vrms.

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 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

Ref. Certif. No.

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

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)

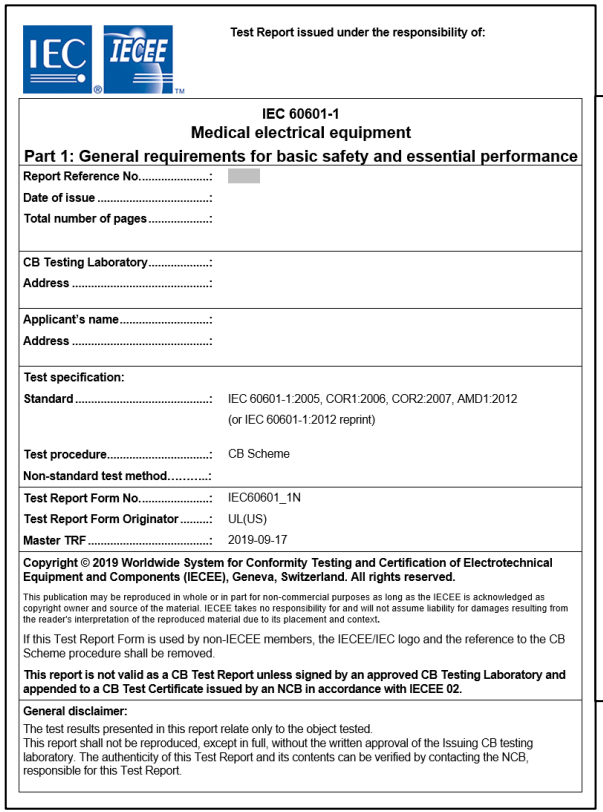
☐ Additional Information on page 2

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......: [redacted]

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)

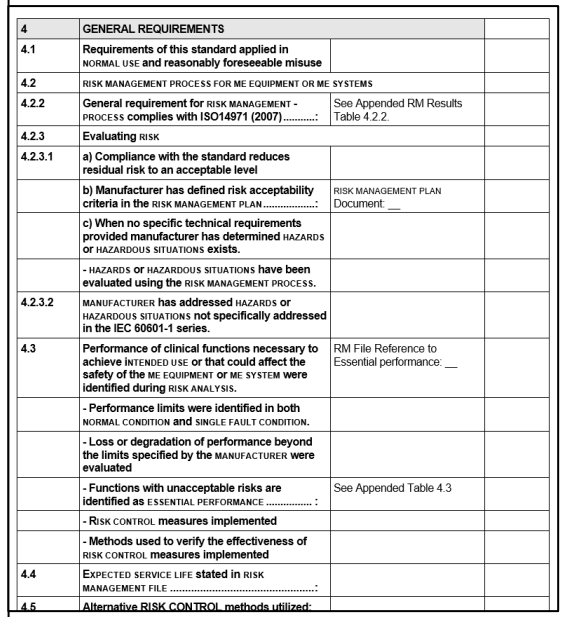
Master TRF.....: 2019-09-17

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:		

Otras Consideraciones

- Ciberseguridad
  - IEC 62443
- *Seguridad Funcional*
  - IEC 61508
- *Competencias del Personal*

Un enfoque metódico

… a la Regulación de Dispositivos Médicos

- Participar
- Objeto de la Evaluación de la Conformidad
- Requisitos especificados
- Actividad de la Evaluación de la Conformidad
- Sistema/Esquema de Evaluación de la Conformidad
- Optimización Global


IEC
IECEE
TM

IMDRF International Medical Device Regulators Forum

- Australia Therapeutic Goods Administration
- Brasil National Health Surveillance Agency (ANVISA)
- Canadá Health Canada
- China China Food and Drug Administration
- Unión Europea European Commission Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
- Japón Pharmaceuticals and Medical Devices Agency y el Ministry of Health, Labour and Welfare
- Rusia Russian Minstry of Health
- Singapur Health Sciences Authority
- Corea del Sur Ministry of Food and Drug Safety
- Estados Unidos de América US Food and Drug Administration

IEC®

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Utilización de normas voluntarias de consenso y evaluación de la conformidad

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