# TECHNICAL REPORT

# IEC TR 61010-3-042

First edition 1999-10

Safety requirements for electrical equipment for measurement, control, and laboratory use –

Part 3-042: Conformity verification report for IEC 61010-2-042:1997, Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes

*Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire –* 

Partie 3-042: Rapport de vérification de la conformité de la CEI 61010-2-042:1997, Prescriptions particulières pour autoclaves et stérilisateurs utilisant des gaz toxiques pour le traitement des matériels à usage médical et durant les procédés de traitement de laboratoire



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- IEC Bulletin Available both at the IEC web site\* and as a printed periodical

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\* See web site address on title page.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

## SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE –

## Part 3-042: Conformity verification report for IEC 61010-2-042:1997, Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes

## FOREWORD

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IEC 61010-3-042, which is a technical report, has been prepared by IEC technical committee 66: Safety of measuring, control, and laboratory equipment.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
66/194/CDV	66/218/RVC

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

This report is a Technical Report and is of a purely informative nature and is therefore by itself not to be regarded as an International Standard. It is for use by testhouses and other users to assist them with determining and recording verification of conformity of the equipment under test with the requirements of:

IEC 61010-2-042: 1997,

and

IEC 61010-1: 1990 + amendment 1: 1992 + amendment 2: 1995

The protocol for completion of this report is contained in publication IEC 61010-3:1997.

The IEC sells read-only PDF files as a general rule. In the present instance, and quite exceptionally, to enable the user to fill in the forms, a revisable file is included in a pocket affixed to the back cover of this publication.

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A bilingual version will not be issued.

A French version may be issued.

Conformity Verification Report IEC 61010-2-042 Safety requirements for electrical equipment for measurement, control, and laboratory use: Part 2-042: Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes				
Report reference No:				
Compiled by (+ signature):				
Approved by (+ signature):				
Date of issue:				
Testing organization:				
Address:				
Testing location:				
Applicant:				
Address:				
Standard:	IEC 61010-1:1990 + amendment 1:1992+ amendment 2:1995 IEC 61010-2-042: 1997			
Copyright blank test report:	This report has been prepared by IEC/TC 66, which retains responsibility for any changes or corrections required.			
Test procedure:				
Procedure deviation				
Non-standard test method:				
Type of item tested:	Measurement     Control     Laboratory			
Trademark:				
Model/type référence:				
Manufacturer:				
Rating:				
Copy of rating plate:				

Description of equipment function:							
INSTALLATION/OVERVOLTAGE CATEGOR	RY:						
POLLUTION DEGREE:							
Environmental rating:		Standard		Other (specify):			
Equipment mobility:		Portable Built in		Hand-held Benchmounted		Floorstanding Other (specify):	Fixed
Connection to mains supply:		Permanent		Detachable		Non-detachable	None
Operating conditions:		Continuous		Short-time		Intermittent	
Overall size of the equipment (Length × Width × Height): Mass of the equipment (kg): Marked degree of protection to IEC 60529: IP							
Accessories and detachable parts i	ncluc	led in the eva	aluati	on:			
Options:							
NOTE "(see Form A.X)" refers to a form appended to the report.							

Document No.	Document description	Number of pages

## Table 1 – Documents attached to this report

- 7 -

	-	Equipment	Calibra	tion date	
ltem	Туре	No.	Last <sup>1)</sup>	Due	Comments

1) or interval between calibrations.

### Table 2 – Test equipment list

## Table 3 – List of components relied on for safety

Unique component reference or location (including drawing reference if required)	Application/Function	Manufacturer and part number (note 1)	RATING (note 2)	Licence number, file number or other documentary evidence of acceptance	
NOTE 1 List all manufacturers concerned. NOTE 2 Electrical, mechanical, flammability, etc.					

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Clause Subclause	Requirement	Result	Comments
5	Marking and documentation		
5.1.1	General Required equipment markings are		
	a) visible		
	<ul> <li>from the exterior</li> <li>or</li> <li>after removing a cover</li> <li>or</li> <li>opening a door</li> <li>or</li> </ul>		
	<ul> <li>after removal from a rack or panel</li> <li>b) not put on parts which can be removed by an OPERATOR</li> </ul>		
	<ul><li>c) Letter symbols (IEC 60027) used</li><li>d) Graphic symbols</li></ul>		
5.1.2	(IEC 61010-1, Table 1) used		
	Equipment is identified by		
	<ul> <li>manufacturer's name or registered trade mark</li> </ul>		
	- model number, name or other means		
	<ul> <li>PRESSURE VESSEL markings (see 5.1.102)</li> </ul>		
	If jacket pressure differs from CHAMBER, data for both marked on PRESSURE VESSEL		
5.1.3	Mains supply		
	Equipment is marked as follows:		
	a) nature of supply:		
	<ul> <li>a.c. RATED mains frequency or range of frequencies</li> </ul>		
	<ul> <li>d.c. with symbol 1</li> </ul>		
	b) RATED supply voltage(s) or range		
	<ul> <li>c) – maximum RATED power (W or VA) or input current</li> </ul>		
	If more than one voltage range:		
F	<ul> <li>separate values marked</li> <li>or</li> <li>values differ by less than 20 % (see Form A.3)</li> </ul>		

Clause Subclause	Requirement	Result	Comments
	<ul> <li>d) equipment which can be set for different RATED supply voltages:</li> </ul>		
	<ul> <li>for PORTABLE EQUIPMENT, indication is visible from the exterior</li> </ul>		
	<ul> <li>if the supply voltage can be altered without the use of a tool, changing the setting also changes the indication</li> </ul>		
	<ul> <li>e) accessory mains socket-outlets accepting standard mains plugs are marked</li> </ul>		
	<ul> <li>with the voltage if it is different from the mains supply voltage</li> </ul>		
	<ul> <li>for use only with specific equipment</li> </ul>		
	If not marked for specific equipment it is marked with		
	<ul> <li>the maximum RATED current or power, and maximum permitted leakage current</li> </ul>		
	or – symbol 14 with full details in the documentation		
F	The measured value not more than 110 % (see Form A.3)		
5.1.4	Fuses		
	OPERATOR replaceable fuse marking (see also 5.4.5)		
5.1.5	Measuring circuit TERMINALS		
	RATED maximum working voltage or current marked		
	Unless clear indication that below limits:		
	<ul> <li>maximum RATED voltage to earth is marked</li> </ul>		
	or – for specific connection only, and means for identifying provided		
	<ul> <li>is adjacent to TERMINALS</li> <li>or</li> </ul>		
	<ul> <li>if insufficient space:</li> </ul>		
	<ul> <li>on the RATING plate or scale plate</li> <li>or</li> <li>if the TERMINAL is marked with symbol 14</li> </ul>		
	INSTALLATION CATEGORY marked		
	TERMINALS permanently connected and not ACCESSIBLE		

Comments

Requirement	Result
TERMINALS and operating devices	
Where necessary for safety, indication of purpose of TERMINALS, connectors, controls and indicators	
Mains supply TERMINALS identified	
Power supply switch on or off position marked if used as disconnecting device	
TERMINAL marking:	
a) FUNCTIONAL EARTH TERMINALS	
b) PROTECTIVE CONDUCTOR TERMINALS:	
<ul> <li>symbol 6 is placed close to or on the TERMINAL</li> </ul>	
or – part of appliance inlet	
c) TERMINALS of measuring and control circuits	
d) TERMINALS supplied from the interior	
e) ACCESSIBLE FUNCTIONAL EARTH TERMINALS	
aa) NORMAL USE setting a control could cause a harzard, an indicating device is provided	
Equipment protected by DOUBLE INSULATION or REINFORCED INSULATION	
Protected throughout (symbol 11 used)	
Only partially protected (symbol 11 not used)	
Battery charging	
Equipment with means to charge rechargeable batteries is marked:	
<ul> <li>to warn against the charging of non- rechargeable batteries</li> </ul>	
<ul> <li>to indicate the type of rechargeable battery used</li> </ul>	
Overpressure safety device	
Identification includes	
<ul> <li>model number, etc.</li> </ul>	
<ul> <li>pressure setting</li> </ul>	

if bursting disc:

Clause

Subclause

5.1.6

5.1.7

5.1.8

5.1.101

- pressure
- temperature

Clause Subclause	Requirement	Result	Comments
5.1.102	PRESSURE VESSEL markings		
	Markings comply with the regulations and codes applicable in the country of intended use		
	In all cases, markings include		
	a) name of the manufacturer		
	b) serial number		
	c) identification number of door (may be the same as the serial number)		
	d) maximum working pressure		
	e) maximum working temperature		
	f) minimum working pressure		
	g) test pressure		
	h) construction standard applies		
	i) the CHAMBER volume in litres		
5.2	Warning markings		
	<ul> <li>visible when ready for NORMAL USE</li> </ul>		
	<ul> <li>if necessary marked with symbol 14</li> </ul>		
	<ul> <li>are near or on applicable parts</li> </ul>		
	<ul> <li>statement to isolate or disconnect</li> </ul>		
	<ul> <li>advice on how to avoid contact with ACCESSIBLE HAZARDOUS LIVE parts</li> </ul>		
	<ul> <li>TERMINAL voltage exceeding 1 kV (symbol 12)</li> </ul>		
	<ul> <li>easily touched high-temperature parts (symbol 13)</li> </ul>		
	<ul> <li>instruction to lock and retain key</li> </ul>		
	<ul> <li>to indicate any hazardous properties of the sterilant gas</li> </ul>		
	<ul> <li>LOAD type warning</li> </ul>		
5.3	Durability of markings		
F	The required markings remain clear and legible in NORMAL USE (see Form A.4)		

Clause Subclause	Requirement	Result	Comments
5.4	Documentation		
5.4.1	General		
	Equipment is accompanied by documentation which includes		
	<ul> <li>technical specification</li> </ul>		
	<ul> <li>instructions for use</li> </ul>		
	<ul> <li>name and address of manufacturer or supplier</li> </ul>		
	<ul> <li>PRESSURE VESSEL conformity declaration</li> </ul>		
	<ul> <li>emergency guidelines</li> </ul>		
	- instructions on warning signs for country of use		
	Definition of INSTALLATION CATEGORY		
	Warning statements and a clear explanation of warning symbols:		
	<ul> <li>provided in the documentation</li> </ul>		
	or – information is marked on the equipment		
5.4.2	Equipment RATINGS		
	Documentation includes		
	<ul> <li>supply voltage or voltage range</li> </ul>		
	<ul> <li>frequency or frequency range</li> </ul>		
	<ul> <li>power or current RATING</li> </ul>		
	<ul> <li>a description of all input and output connections</li> </ul>		
	<ul> <li>RATING of insulation of external circuits, when such circuits are nowhere ACCESSIBLE</li> </ul>		
	<ul> <li>statement of the range of environmental conditions</li> </ul>		
	- the RATED maximum leak rate:		
	a) air in		
	b) air or sterilant out		
5.4.3	Equipment installation		
	Documentation includes instructions for		
	<ul> <li>assembly, location and mounting</li> </ul>		
	<ul> <li>protective earthing</li> </ul>		
I	1		1

Clause Subclause	Requirement	Result	Comments
	<ul> <li>connections to supply</li> </ul>		
	<ul> <li>ventilation requirements</li> </ul>		
	<ul> <li>special services</li> </ul>		
	<ul> <li>maximum sound power level</li> </ul>		
	<ul> <li>instructions about sound pressure</li> </ul>		
	Additional for permanently connected equipment:		
	<ul> <li>supply wiring</li> </ul>		
	<ul> <li>any external switch or circuit-breaker (including location)</li> </ul>		
	<ul> <li>any external overcurrent protection</li> </ul>		
5.4.3.1	Assembly and installation instructions		
	Instructions include		
	a) – location		
	– mounting		
	<ul> <li>maintenance space</li> </ul>		
	b) – component weights		
	<ul> <li>overall weight</li> </ul>		
	c) floor loading		
	d) assembly		
	e) – mains supply		
	<ul> <li>mains connections</li> </ul>		
	f) protective earthing		
	g) – sound power data		
	<ul> <li>sound power requirements</li> </ul>		
	h) hazardous gas atmospheres		
5.4.3.2	Requirements for special services		
	Installation instructions for		
	a) non-recirculating ventilation system		
	b) separate space ventilation sensing device		
	c) non-recirculating local exhaust system		
	d) drainage system		

Clause Subclause	Requirement	Result	Comments
	e) drain venting system		
	f) CHAMBER exhaust system		
	g) – steam supply		
	– steam drain		
5.4.3.3	For permanently connected equipment		
	<ul> <li>external switch or circuit breaker</li> </ul>		
	<ul> <li>external overcurrent protection device</li> </ul>		
5.4.4	Equipment operation		
5.4.4.1	Instructions for use		
	Include		
	a) operating controls:		
	<ul> <li>identification</li> </ul>		
	– use		
	<ul> <li>b) not to be positioned so that disconnection is difficult</li> </ul>		
	c) accessories:		
	<ul> <li>interconnection</li> </ul>		
	– suitability		
	<ul> <li>detachable parts</li> </ul>		
	<ul> <li>special materials</li> </ul>		
	d) limits for intermittent operation		
	e) explanation of symbols used		
	f) cleaning		
	g) lockable door closure stop:		
	<ul> <li>correct use</li> </ul>		
	– retain key		
	h) safe use of the overide key		
	i) action in case of malfunction		
5.4.4.2	Consumable materials		
	Instructions given for inspection, replacement and storage		

Clause Subclause	Requirement	Result	Comments
5.4.4.3	OPERATOR training		
	Instructions for RESPONSIBLE BODY:		
	a) to arrange operation and safety training		
	b) to supervise sterilization procedures		
	<ul> <li>comprehensive instructions for personnel working with toxic gas:</li> </ul>		
	<ul> <li>health hazard</li> </ul>		
	<ul> <li>national regulations</li> </ul>		
	– safe use		
	<ul> <li>leak detection</li> </ul>		
	d) in-service programmes:		
	– conducted		
	<ul> <li>attendance records</li> </ul>		
	<ul> <li>evidence of understanding</li> </ul>		
5.4.5	Equipment maintenance		
	Instructions include		
	<ul> <li>special precautions for safety</li> </ul>		
	<ul> <li>threaded parts</li> </ul>		
	<ul> <li>safety devices</li> </ul>		
	<ul> <li>sufficient preventive maintenance and inspection information</li> </ul>		
	<ul> <li>replacement of hoses, etc.</li> </ul>		
	<ul> <li>specific battery type</li> </ul>		
	<ul> <li>any manufacturer specified parts</li> </ul>		
	<ul> <li>RATING and characteristics of fuses</li> </ul>		
6 F	Protection against electric shock (see Form A.5)		
6.1	General		
	Conformity is checked by the determination of 6.2 and 6.3 followed by the tests of 6.4 to 6.12		
	Asbestos not used		
6.1.1	Exceptions		
F	Capacitance test (see Forms A.6 and A.7)		

Clause Subclause	Requirement	Result	Co
6.2 F	Determination of ACCESSIBLE parts (see Form A.6)		
6.3	Permissible limits for ACCESSIBLE parts		
6.3.1 F	Values in NORMAL CONDITION (see Form A.7)		
6.3.2 F	Values in SINGLE FAULT CONDITION (see Form A.8)		
6.4	<b>Protection in NORMAL CONDITION</b> (see 6.8 and 8.1)		
6.5	Protection in SINGLE FAULT CONDITION		
	Additional protection is provided by		
	- one or more of 6.5.1 to 6.5.3		
	or – automatic disconnection of the supply		
6.5.1	Protective earthing		
	ACCESSIBLE conductive parts:		
	<ul> <li>bonded to the protective conductor terminal</li> </ul>		
	or – separated by screen or BARRIER from parts which are HAZARDOUS LIVE		
	(For indirect bonding of measurement and test equipment, see 6.5.1.4)		
6.5.1.1	PROTECTIVE BONDING		
	<b>PROTECTIVE BONDING</b> consists of directly connected structural parts or discrete conductors or both; and withstands thermal and dynamic stresses		
6.5.1.2 F	Bonding impedance of plug-connected equipment (see Form A.9)		
6.5.1.3 F	Bonding impedance of PERMANENTLY CONNECTED EQUIPMENT (see Form A.9)		
6.5.1.4 F	Indirect bonding for measuring and test equipment (see Form A.9)		
6.5.2	DOUBLE INSULATION and REINFORCED INSULATION (see 6.7, 6.8 and 6.9.2)		
6.5.3 F	PROTECTIVE IMPEDANCE (see Form A.10)		
	Components wires and connections are RATED as required		

Clause Subclause	Requirement	Result	Comments
6.5.4	Built-in panel meters		
	If, after building in, the requirements of 6.5.1 to 6.5.3 are not met, the panel meter		
	<ul> <li>has no ACCESSIBLE conductive parts</li> </ul>		
	<ul> <li>has basic insulation of ACCESSIBLE surfaces</li> </ul>		
	<ul> <li>has DOUBLE/REINFORCED INSULATION of ACCESSIBLE surface of parts intended to be grasped</li> </ul>		
6.6	External circuits		
6.6.1 F	Separation of internal circuits (see list in Forms A.1 and A.5)		
	If the other internal circuit exceeds the values of 6.3.2 in NORMAL CONDITION and only BASIC INSULATION:		
	a) short circuit could not make external circuit HAZARDOUS LIVE		
	b) manufacturer's instructions include		
	<ul> <li>a statement that the TERMINAL for external circuits is for use only with equipment which has no live parts which are ACCESSIBLE</li> </ul>		
	<ul> <li>the RATING of the insulation required for external circuits</li> </ul>		
	<ul> <li>the connection to be used at the remote end of external circuits</li> </ul>		
	<ul> <li>the type of equipment which may be connected to the TERMINAL</li> </ul>		
6.6.2	TERMINALS for external circuits		
	ACCESSIBLE TERMINALS are not HAZARDOUS LIVE except as permitted by 6.1.1		
	The following terminals are not hazardous live:		
	- PROTECTIVE CONDUCTOR TERMINALS		
	- FUNCTIONAL EARTH TERMINALS		
	<ul> <li>headphone TERMINALS</li> </ul>		
F	TERMINALS which receive a charge from an internal capacitor (see Form A.7)		
	High-voltage TERMINALS energized from the interior are		
	- not ACCESSIBLE		
	or – marked		

Clause Subclause	Requirement	Result	Comments
6.6.3	Circuits with TERMINALS which are HAZARDOUS LIVE		
	These circuits		
	<ul> <li>are not connected to ACCESSIBLE conductive parts</li> </ul>		
	or – are connected to ACCESSIBLE conductive parts, but are not mains circuits and have one TERMINAL contact at earth potential		
	No ACCESSIBLE conductive parts are HAZARDOUS LIVE		
6.7 F	CLEARANCES and CREEPAGE DISTANCES (see annex D of IEC 61010-1 and Form A.11)		
6.8 F	<b>Dielectric strength tests</b> (see annex E of IEC 61010-1 and Form A.12)		
	Protection against the spread of fire (see 9.1)		
6.9	Constructional requirements for protection against electric shock		
6.9.1	General		
	In circuits exceeding the values of 6.3.2:		
	<ul> <li>security of wiring connections</li> </ul>		
	<ul> <li>screws securing removable covers</li> </ul>		
	<ul> <li>accidental loosening</li> </ul>		
6.9.2	ENCLOSURES of equipment with DOUBLE INSULATION OF REINFORCED INSULATION		
	ENCLOSURE surrounds all metal parts except for small metal parts which are separated		
	ENCLOSURES or parts made of insulating material		
	Protection for metal ENCLOSURES or parts by:		
	- PROTECTIVE IMPEDANCE		
	or – an insulating coating or BARRIER on the inside		
	or - CLEARANCES and CREEPAGE DISTANCES cannot be reduced by loosening of parts or wires		
6.9.3	Equipment using PROTECTIVE BONDING		
	a) OPERATOR removable parts		
	b) Movable conductive connections		
	c) Exterior metal braids of cables		

Clause Subclause	Requirement	Result	Comments
	d) Mains passed through the equipment		
	e) Protective earthing conductors green/yellow		
	Exceptions:		
	<ul> <li>earthing braids</li> </ul>		
	<ul> <li>internal protective conductors</li> </ul>		
	f) Equipment using PROTECTIVE BONDING		
6.9.4	Over-range indication		
	Unambiguous		
6.10	Connection to mains supply source and connections between parts of equipment		
6.10.1	Mains supply cords		
	RATED for maximum equipment current (see 5.1.3 c))		
	Cable complies with IEC 60227 or IEC 60245 or is a certified cord		
	Heat resistant if likely to contact hot parts		
	Temperature RATING (cord and inlet)		
	Green/yellow used only for connection to PROTECTIVE CONDUCTOR TERMINALS		
	Detachable cords with IEC 60320 mains connectors		
	<ul> <li>comply with IEC 60799</li> </ul>		
	or – have the current RATING of the mains connector		
6.10.2	Fitting of non-detachable mains supply cords		
6.10.2.1	Cord entry		
	Non-detachable cord protection:		
	<ul> <li>inlet smoothly rounded with radius ≥1,5 D</li> </ul>		
	or – insulated cord guard protruding ≥5 D		
6.10.2.2	Cord anchorage		
	The protective earth conductor is the last to take the strain		
	Cord anchorages:		
	<ul> <li>the cord is not clamped by direct pressure from a screw</li> </ul>		

Clause Subclause	Requirement	Result	Comments
	<ul> <li>knots are not used</li> </ul>		
	<ul> <li>cannot push the cord into the equipment to cause a hazard</li> </ul>		
	<ul> <li>no failure of cord insulation in anchorage with metal parts</li> </ul>		
	<ul> <li>compression bushing:</li> </ul>		
	<ul> <li>a) clamps all types and sizes of mains cords and</li> <li>b) is suitable:</li> </ul>		
	i) for connection to TERMINALS provided or		
	ii) it is designed for screened mains cord		
	<ul> <li>cord replacement does not cause a hazard and method of strain relief is clear</li> </ul>		
F	Push-pull test (see Form A.13)		
6.10.3	Plugs and connectors		
	<ul> <li>Mains supply plugs, connectors etc., comply with relevant specifications</li> </ul>		
	b) If equipment supplied at voltages below 6.3.2.1:		
	<ul> <li>plugs of mains supply cords do not fit mains sockets above RATED supply voltage</li> </ul>		
	<ul> <li>mains type plugs used only for connection to mains supply</li> </ul>		
F	<ul> <li>c) Plug pins which receive a charge from an internal capacitor (see Form A.7)</li> </ul>		
	d) Accessory mains socket outlets:		
	<ul> <li>if a standard mains plug is accepted, there is a marking (see 5.1.3e))</li> </ul>		
	<ul> <li>input has a protective earth conductor if outlet has earth TERMINAL contact</li> </ul>		
6.11	TERMINALS		
6.11.1	Accessible terminals		
	a) No risk of accidental contact (see also 5.1.6 c))		
	b) Will not work loose		
l	I		l

Clause Subclause	Requirement	Result	Comments
6.11.2	PROTECTIVE CONDUCTOR TERMINAL		
	a) Appliance inlet (no requirement)		
	<ul> <li>b) For rewirable cords and PERMANENTLY CONNECTED EQUIPMENT, PROTECTIVE CONDUCTOR TERMINAL is close to mains supply TERMINALS</li> </ul>		
	<ul> <li>c) If no mains supply is required, any PROTECTIVE CONDUCTOR TERMINAL is</li> </ul>		
	<ul> <li>near TERMINALS of circuit for which protective earthing is necessary</li> </ul>		
	<ul> <li>external if other TERMINALS external</li> </ul>		
	<ul> <li>Equivalent current-carrying capacity to mains supply TERMINALS</li> </ul>		
	e) Soldered connections:		
	<ul> <li>independently secured</li> </ul>		
	<ul> <li>not used for other purposes</li> </ul>		
	<ul> <li>screw connections are secured</li> </ul>		
	f) Contact surfaces are metal		
	g) If plug-in, makes first and breaks last		
	h) Protective conductor of measuring circuit:		
	– current RATING		
	<ul> <li>protective bonding:</li> </ul>		
	i) not interrupted or		
	ii) indirect bonding		
6.11.3	FUNCTIONAL EARTH TERMINALS		
	Independent connection		
6.11.101	Connection of non-detachable mains cords to TERMINALS		
	Does not require special preparation of the conductors		
6.12	Disconnection from supply source		
6.12.1	General		
	Disconnection device provided		
6.12.1.1	Exception to 6.12.1		
	Short circuit or overload cannot cause a hazard		

Clause Subclause	Requirement	Result	Comments
6.12.2	Requirements according to type of equipment		
6.12.2.1	PERMANENTLY CONNECTED EQUIPMENT		
	<ul> <li>switch or circuit-breaker is part of the equipment</li> </ul>		
	or – documentation specifies switch location and marking		
6.12.2.2	Single-phase cord-connected equipment		
	<ul> <li>switch or circuit-breakers</li> </ul>		
	or – appliance coupler (disconnectable without TOOL)		
	or – separable plug (without locking device)		
6.12.2.3	Hazards arising from function		
	Emergency switch		
	Emergency switch ≤1 m from the moving part		
6.12.3	Disconnecting devices		
	Electrically close to the supply		
6.12.3.1	Switches and circuit-breakers		
	When used as disconnection device:		
	<ul> <li>meets IEC 60947-1 and IEC 60947-3</li> </ul>		
	<ul> <li>contact separation</li> </ul>		
	<ul> <li>contact position evident in off position</li> </ul>		
	<ul> <li>marked to indication function</li> </ul>		
	<ul> <li>not incorporated in mains cord</li> </ul>		
	<ul> <li>does not interrupt protection earth conductor</li> </ul>		
	<ul> <li>if has other contacts, meets separation requirements of 6.6 and 6.7</li> </ul>		
6.12.3.2	Appliance couplers and plugs		
	Where an appliance coupler or separable plug is used as the disconnecting device (see 6.12.2.2):		
	<ul> <li>readily identifiable and easily reached by the OPERATOR</li> </ul>		
	- single-phase PORTABLE EQUIPMENT cord length $\leq 3 \text{ m}$		
	Protective earth conductor connected first and disconnected last		
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Clause Subclause	Requirement	Result	Comments
6.12.101	Disconnection by interruption of the mains supply		
F	Power interruption and partial interruption (see Form A.1, 7.2.101.4 and 11.102)		
7	Protection against mechanical hazards		
7.1	General		
	Conformity is checked by 7.2 to 7.5		
7.1.101	Door closure and retaining mechanism		
	SINGLE FAULT CONDITION		
	Threaded parts		
7.2	Moving parts		
	Moving parts not able to crush, etc. (see also 6.12.2.3)		
	If <b>OPERATOR</b> access permitted:		
	a) access requires TOOL		
	b) statement about training		
	c) warning markings or symbol 14		
7.2.101	Powered doors		
7.2.101.1	Shut-down device		
	a) residual movement		
	b) returns to safe condition		
	c) key, etc. for reset		
7.2.101.2	Door motion reversal and stoppage		
F	Device reverses the motion of the door upon encountering an obstruction (see Form A.30)		
7.2.101.3	Sliding doors		
F	Door speed and distance (see Form A.30)		
7.2.101.4	Interruption of the mains supply		
	Does not cause any safety system to be circumvented and no hazard arises		

Clause Subclause	Requirement	Result	Comments
7.3	Stability		
	Marking of non-automatic means		
	Conformity tests:		
	<ul> <li>10° tilt test</li> </ul>		
	<ul> <li>multi-directional force test</li> </ul>		
	<ul> <li>downward force test</li> </ul>		
7.4	Provisions for lifting and carrying		
	Handles or grips withstand four times mass		
	Equipment ≥18 kg:		
	<ul> <li>has means for lifting or carrying</li> </ul>		
	or – directions in documentation		
7.4.101	Provisions for transferring the LOAD into and out of the CHAMBER		
	Protection against mechanical hazards		
	LOAD location and retention		
	Prevention of shelf tilting or disengaging		
7.5	Expelled parts		
	Equipment contains or limits the energy		
	Protection not removable without the aid of a TOOL		
7.101	Door interlocks		
7.101.1	General		
	Interlocks prevent:		
	a) hazardous access, 1 000 N applied		
	b) no gas enters CHAMBER until door secured		
	c) interlock failure OPERATING CYCLE prevented		
	d) pressure-retaining parts not fully released until CHAMBER vented		
	e) seal not broken before pressure within 0,2 bar of atmospheric (>50 bar·litres)		
	f) AUTOCLAVES <50 bar-litres		
	– meet a), c) and d) above		
	or – vent CHAMBER before access to the door release		

Clause Subclause	Requirement	Result	Comments
7.101.2	Door interlocks for double-ended AUTOCLAVES		
	OPERATOR cannot operate remote door (except automatic loading where OPERATOR not involved)		
7.102	Doors with inflatable or pressure-activated seals		
	If pressure falls below minimum:		
	a) OPERATING CYCLE terminates		
	b) alarm indicates fault condition		
	c) door remains closed and gas does not escape		
	d) ventilation operates		
	<ul> <li>e) sterilant gas isolating valve automatically operated</li> </ul>		
	<ul> <li>f) complete system is evacuated to the discharge pipe</li> </ul>		
	<li>g) if sterilant is flammable, system is purged using air or inert gas</li>		
	h) no hazard is caused		
7.103	Prevention of door closure		
	Device to prevent door closing, with lock and dedicated key or		
	<ul> <li>Emergency shutdown control operable from within the CHAMBER</li> </ul>		
	or $-$ CHAMBER depth < 0,7 m and volume < 0,4 m <sup>3</sup>		
8	Mechanical resistance to shock and impact		
F	After the tests of 8.1 to 8.4 (see Form A.11):		
F	<ul> <li>voltage tests (see Form A.12)</li> </ul>		
	<ul> <li>inspection, equipment meets the following requirements:</li> </ul>		
	a) hazardous live parts not ACCESSIBLE		
	b) ENCLOSURE shows no cracks (hazard)		
F	c) CLEARANCES not less than their permitted values (see Form A.11)		
	<ul> <li>BARRIERS not damaged or loosened</li> </ul>		
	<ul> <li>no moving parts exposed, except as permitted by 7.2</li> </ul>		
	<ul> <li>no damage which could cause spread of fire</li> </ul>		

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Clause Subclause	Requirement	Result	Comments
9	Equipment temperature limits and protection against the spread of fire		
9.1	General		
	Conformity is checked by		
F	or – measurement of CREEPAGE DISTANCE and CLEARANCE and the voltage tests of annex G (see Form A.14)		
F	or – method of annex F (see Forms A.15, A.16 and A.17)		
	Asbestos not used for thermal insulation		
9.2	Temperature tests		
9.3	Guards		
F	Surfaces liable to exceed 100 °C (see Form A.18):		
	<ul> <li>protected by guards</li> <li>or</li> <li>marked</li> <li>or</li> </ul>		
	<ul> <li>intended to be hot (see 9.1)</li> </ul>		
	Guards not removable without TOOL		
9.4	Field-wiring TERMINAL boxes		
	Temperature RATING of the cable is:		
F	<ul> <li>marked (see Form A.18)</li> <li>and         <ul> <li>adjacent to field-wiring TERMINALS</li> <li>or</li> <li>visible during and after installation</li> </ul> </li> </ul>		
9.5	Overtemperature protection devices		
F	<ul> <li>fitted, to operate in SINGLE FAULT CONDITION (see Form A.1)</li> </ul>		
	– meets 14.3		
	<ul> <li>does not operate in NORMAL USE (see 3.5.6)</li> </ul>		
	<ul> <li>if self-resetting, can only be set to operate in SINGLE FAULT CONDITION</li> </ul>		

Clause Subclause	Requirement	Result	Comments
	Overtemperature protection:		
	<ul> <li>separate from temperature control</li> </ul>		
	<ul> <li>not self-resetting</li> </ul>		
	<ul> <li>does not require soldering for resetting</li> </ul>		
9.6	Overcurrent protection		
9.6.1	PERMANENTLY CONNECTED EQUIPMENT		
	Device		
	<ul> <li>fitted within the equipment or</li> </ul>		
	<ul> <li>specified in manufacturer's instructions</li> </ul>		
9.6.2	Other equipment		
	Protection within the equipment		
	Devices not in the protective conductor		
	Fuses or single-pole circuit-breakers not fitted in neutral (multi-phase)		
10	Resistance to heat		
10.1 F	Integrity of clearance and creepage distances (see Form A.11)		
10.2 F	<b>Resistance to heat of non-metallic ENCLOSURE</b> (see Form A.19)		
10.3	Resistance to heat of insulation material		
	Parts supporting		
	<ul> <li>parts connected to mains supply</li> </ul>		
	- TERMINALS carrying >0,5 A		
11	Protection against hazards from fluids		
11.1	General		
11.2 F	Cleaning (see Form A.20)		
11.3 F	Spillage (see Form A.20)		
11.4 F	Overflow (see Form A.20)		
11.5	Battery electrolyte		
	Battery electrolyte leakage presents no hazard		
11.6 F	Specially protected equipment (see Form A.20)		

Clause Subclause	Requirement	Result	Comments
11.7	Fluid pressure and leakage		
11.7.1	Maximum pressure not exceeded		
11.7.2 F	Leakage and rupture at high pressure (see Form A.21)		
	Test to IEC 60335 (refrigeration only)		
11.7.3 F	Leakage from low-pressure parts (see Form A.21)		
11.7.4	Overpressure safety device		
	Where possible to exceed maximum CHAMBER working pressure:		
	<ul> <li>overpressure device fitted</li> </ul>		
	and − device set to operate at a pressure ≤ the maximum working pressure		
	<ul> <li>does not exceed maximum working pressure by more than 10 %</li> </ul>		
	<ul> <li>no discharge during NORMAL USE</li> </ul>		
	<ul> <li>no accumulation of water on seating</li> </ul>		
	<ul> <li>discharge to a safe place</li> </ul>		
	Does not operate in NORMAL USE and Complies with the following:		
	<ul> <li>positioned close to parts intended to be protected</li> </ul>		
	<ul> <li>mounted according to instructions</li> </ul>		
	<ul> <li>connected by the shortest length of pipe</li> </ul>		
	<ul> <li>access for inspection, maintenance and repair</li> </ul>		
	<ul> <li>adjustment only with TOOL</li> </ul>		
	<ul> <li>no discharge to person</li> </ul>		
	<ul> <li>no hazard from discharge</li> </ul>		
	<ul> <li>sufficient discharge capacity</li> </ul>		
	<ul> <li>no shut-off valve between protective device and protected parts</li> </ul>		

Clause Subclause	Requirement	Result	Comments
11.7.101	Instruments and indicating devices		
	If necessary for safety:		
	a) CHAMBER pressure indicator		
	b) jacket pressure indicator		
	c) OPERATING CYCLE counter		
	d) supply line pressure indicator		
	e) leak detection		
F	Indicators operate in SFC (see Form A.2)		
11.101	Discharge from pressure-venting valves and overpressure safety devices		
	a) Discharge:		
	– no hazard		
	<ul> <li>pipe requirements</li> </ul>		
	b) Discharge inside cabinet:		
	<ul> <li>cabinet vented</li> </ul>		
	<ul> <li>cannot reach OPERATOR</li> </ul>		
11.102	Interruption of supplies and services		
F	Not cause safety systems to be circumvented and no hazard (see Form A.1)		
12	Protection against radiation, including laser sources, and against sonic and ultrasonic pressure		
12.1	General		
12.2	Equipment producing ionizing radiation		
12.2.1 F	Ionizing radiation (see Form A.22)		
12.2.2	Accelerated electrons		
12.3	Ultra-violet radiation		(Conformity test under consideration)
12.4	Microwave radiation		(Conformity test and limit of 10 W/m <sup>2</sup>
12.5	Sonic and ultrasonic pressure		are under consideration)
	Sound level (see Form A.23)		
	Ultrasonic pressure (see Form A.23)		
12.6	Laser sources (IEC 60825)		

Clause Subclause	Requirement	Result	Comments
13	Protection against liberated gases, explosion and implosion		
13.1	Poisonous and injurious gases		
	<ul> <li>Any data/test reports used to demonstrate conformity attached</li> </ul>		
	b) – parts do not react with sterilant or carrier gas and		
	<ul> <li>liberation of gas does not cause a hazard</li> </ul>		
13.1.101	Chamber leakage		
	<ul> <li>leakage test before sterilant gas admitted</li> </ul>		
	<ul> <li>shutdown if level exceeded</li> </ul>		
13.1.102	Non-return valve in the air inlet pipe		
	Non-return valve operating above atmospheric pressure		
13.1.103	Protection from hazards before any door can be opened		
13.1.103.1	OPERATING CYCLE includes sterilant removal to below flammable limit		
13.1.103.2	Means provided so no hazard when left in a closed unventilated condition		
13.1.104	Protection against gases liberated from the LOAD		
13.1.104.1	The sterilant removal stage is followed by		
	<ul> <li>flushing stage</li> </ul>		
	or – multiple evacuations		
	and – door does not open until completion		
13.1.104.2	No hazard from desorption of sterilant from LOAD		
13.1.105	Failure of CHAMBER exhaust system		
	<ul> <li>audible and visible warning signals</li> </ul>		
	- OPERATING CYCLE is not initiated		
	or – if cycle in progress, access to LOAD prevented until exhaust system is operational		
13.1.106	Failure of space ventilation system		
	Terminals for sensing device		

Requirement	Result	Comments
Failure of sensor or timer		
Visible alarm to indicate hazard		
If failure occurs:		
<ul> <li>OPERATING CYCLE not initiated</li> </ul>		
<ul> <li>or</li> <li>if cycle in progress, access to LOAD prevented until sterilant removed</li> </ul>		
Protection against gases liberated from the drain		
Discharge to a safe place		
Local exhaust ventilation		
Connected to remove fugitive emissions		
Explosion and implosion		
Components		
Components liable to explode:		
<ul> <li>pressure release device</li> </ul>		
<ul> <li>the apparatus incorporates OPERATOR protection (see also 7.5)</li> </ul>		
Pressure release device:		
<ul> <li>discharge without danger</li> </ul>		
<ul> <li>not obstructable</li> </ul>		
Parts do not react with sterilant or carrier gas to cause explosion or implosion		
Batteries		
Explosion or fire hazard:		
<ul> <li>protection incorporated in the equipment</li> </ul>		
<ul> <li>instructions specify batteries</li> </ul>		
<ul> <li>single component cannot cause hazard (short circuit and open circuit)</li> </ul>		
<ul> <li>warning marking or symbol 14</li> </ul>		
Battery compartment design		
Polarity reversal test		
	Failure of sensor or timer         Visible alarm to indicate hazard         If failure occurs:         - OPERATING CYCLE not initiated         or         - if cycle in progress, access to LOAD prevented until sterilant removed         Protection against gases liberated from the drain         Discharge to a safe place         Local exhaust ventilation         Connected to remove fugitive emissions         Explosion and implosion         Components         Components liable to explode:         - pressure release device         or         - discharge without danger         - not obstructable         Parts do not react with sterilant or carrier gas to cause explosion or implosion         Batteries         Explosion or fire hazard:         - protection incorporated in the equipment or         - instructions specify batteries and         - single component cannot cause hazard (short circuit and open circuit) (see Form A.24, including circuit diagram)         - warning marking or symbol 14         Battery compartment design	Failure of sensor or timer         Visible alarm to indicate hazard         If failure occurs:         - OPERATING CYCLE not initiated         or         - if cycle in progress, access to LOAD prevented until sterilant removed         Protection against gases liberated from the drain         Discharge to a safe place         Local exhaust ventilation         Connected to remove fugitive emissions         Explosion and implosion         Components         Components         Components         Components         Components         Consected to remove fugitive emissions         Explosion and implosion         Components         Components         Components         Components         Components         Pressure release device         or         - not obstructable         Parts do not react with sterilant or carrier gas to cause explosion or implosion         Batteries         Explosion or fire hazard:         - protection incorporated in the equipment or         - instructions specify batteries and         - single component cannot cause hazard (short circuit and open circuit) (see Form A.24, including circuit diagram)         - warning marking or symbol 14     <

Comments	Result	Requirement	Clause Subclause
		Heating of sterilant	13.2.101
		<ul> <li>No hazard when containers subject to direct heating</li> </ul>	
		<ul> <li>Sterilant liquids have no direct contact with electrical heating element</li> </ul>	
		<ul> <li>Parts do not have a temperature to cause fire, explosion or other hazard</li> </ul>	
		Flammable sterilants	13.2.102
		<ul> <li>Equipment has no source of ignition</li> </ul>	
		and <ul> <li>OPERATING CYCLE includes air removal stage</li> </ul>	
		Electrical requirements	13.2.103
		Hazardous area classification and requirements	13.2.103.1
		Hazardous area according to IEC 60079:	
		– classified	
		- protected	
		Bonding of electrically conductive components	13.2.103.2
		If explosion hazard under SFC:	l
		- all conductive components earth-bonded	
		<ul> <li>non-conductive components protected against electrostatic discharge</li> </ul>	
		Implosion of high-vacuum devices	13.3
		High-vacuum devices:	
		<ul> <li>intrinsically protected and correctly mounted</li> </ul>	
		or – ENCLOSURE provides protection:	
		<ul> <li>screen not removable without TOOL</li> </ul>	
		<ul> <li>if glass screen, not in contact</li> </ul>	
		CHAMBER exhaust system	13.101
		Discharge no hazard	
		LOAD access after a fault	13.102
		Under SFC:	
		<ul> <li>no safety devices disabled</li> </ul>	
		- no access to LOAD until no hazard	
		- no access to LOAD until no hazard	

Clause Subclause	Requirement	Result	Comments
13.103	Interruption of supplies and services		
F	Interruption or partial interruption of non-electrical supply or service (see Form A.1)		
13.104	Sterilant supply system		
13.104.1	Purging		
	Means to purge before disconnected or opened		
13.104.2	Gas blending		
	Means provided to ensure correct gas mixture		
13.104.3	Supply pipe		
	Each CHAMBER sterilant supply pipe has		
	a) a non-return valve and for flammable sterilants:		
	<ul> <li>a flame arrester</li> <li>or</li> <li>a heat-sensitive cut-off valve</li> </ul>		
	b) automatic and manual shut-off valves		
13.104.4	Sterilant cartridges		
	a) access during OPERATING CYCLE prevented		
	b) means to retain cartridge for puncturing		
13.104.5	Liquid sterilant		
	Means provided to safely dispense, connect and position containers		
	Means provided to prevent excess gas being liberated in the CHAMBER (see also 13.1)		
13.104.6	Isolation of any part of the sterilant supply system		
	Protected by an overpressure safety device		
14	Components		
14.1	General		
	Where safety is involved, components meet relevant requirements (see Table 3 of this report and Figure 5 of IEC 61010-1)		

Clause Subclause 14.2		Requirement	Result	Comments
		Motors		
14.2.1	F	Motor temperatures (see Form A.25)		
		No hazard from stopped motor		
		Loss of one phase no hazard		
14.2.2		Series excitation motors		
14.3		Overtemperature protection devices		
	F	Devices operating in a SINGLE FAULT CONDITION (see Form A.26)		
		and have/are:		
		<ul> <li>reliable function</li> </ul>		
		<ul> <li>RATED to interrupt maximum voltage and current of circuit</li> </ul>		
		<ul> <li>RATED for maximum surface temperature of 4.4.4.2</li> </ul>		
		<ul> <li>RATED for maximum temperature of 9.2 for parts in contact with flammable liquid</li> </ul>		
		<ul> <li>not self-resetting unless protected part cannot function</li> </ul>		
14.4		Fuse holders		
		No access to HAZARDOUS LIVE parts		
14.5		Mains voltage selecting devices		
		Accidental change not possible		
14.6		HIGH INTEGRITY components		
		Used in applicable positions (see Table 3)		
		Complies with IEC publications		
		Not a single electronic device		
14.7		Mains transformers		
14.7.1		Short-circuit tests		
	F	Transformers meet 4.4.4.1 to 4.4.4.3 (see Form A.27)		
14.7.2		Overload tests		
		Transformer:		
		<ul> <li>has overtemperature protection meeting 14.3</li> </ul>		
	F	or – meets 4.4.4.1 to 4.4.4.3 (see Form A.28)		

Clause Subclause	Requirement	Result	Comments
14.8	Overpressure safety devices		
	Meets requirements of ISO 4126-1		
	Bursting disc:		
	<ul> <li>used only with a safety valve</li> </ul>		
	<ul> <li>complies with ISO 6718</li> </ul>		
14.101	PRESSURE VESSEL		
	<ul> <li>complies with applicable PRESSURE VESSEL regulations and codes</li> </ul>		
	or – complies with codes indicated by purchaser		
14.102	Visibility and readability of instruments and indicating devices		
	Safety related indicating devices:		
	<ul> <li>readily seen</li> </ul>		
	<ul> <li>readable at 1 m with 215 lux, except OPERATING CYCLE counters</li> </ul>		
14.103	Control system		
	OPERATOR cannot set to hazardous condition		
	AUTOMATIC CONTROLLER provided with system to control access to system functions		
	No keys, codes or tools for operating cycle:		
	a) initiation		
	b) selection		
	c) manual advance		
	d) changing programme		
	Functions b), c) and d) protected by increasingly severe restraints		
	Not possible to disable safety devices:		
	- USING AUTOMATIC CONTROLLER		
	<ul> <li>using manual advance</li> </ul>		
	Manual mode disables AUTOMATIC CONTROLLER		
14.104	Microprocessors		
	Failure cannot cause a hazard		

Clause Subclause	Requirement	Result	Comments
14.105	I.105 Access ports		
	Access port retained by interlock under 7.101 or Independent interlock provided		
15	Protection by interlocks		
15.1	General		
	Interlocks are designed to remove a hazard before OPERATOR exposed		
15.2	Prevention of reactivation		
15.3	Reliability		
16	Measuring circuits		
16.1 F	Current measuring circuits (see Form A.29)		
Annex K	Routine tests		
	Manufacturer's declaration		

#### Summary of SINGLE FAULT CONDITIONS applied (4.4.2)

(see Form A.2 for details of tests)

Sub- clause	Title		Carried out	Comments
4.4.2.1	PROTECTIVE IMPEDANCE			
4.4.2.2	Protective conductor			
4.4.2.3	Equipment or parts for short-term or intermittent operation			
4.4.2.4	Motors			
4.4.2.5	Capacitors			
4.4.2.6	Mains transformers Attach drawing of mains Txs showing all protective devices (see Forms A.27 and A.28)			
4.4.2.7	Outputs			
4.4.2.8	Equipment for more than one supply			
4.4.2.9	Cooling – air holes closed – fans stopped – coolant stopped			
4.4.2.10	Heating devices – timer overridden – temperature controller overridden – loss of cooling liquid			
4.4.2.11	Insulation between circuits and parts			
4.4.2.12	Interlocks			
4.4.2.101	Failure or partial failure of mains supply			
4.4.2.102	Failure of other supplies			
List below 4.4.2.1 to 4	all SINGLE FAULT CONDITIONS not covered by			
4.4.2.1 10				

4.4	<b>Testing in SINGLE FAULT CONDITION – Results</b>	
-----	--	--

Test subclause	Fault No.	Fault description	T <sub>d</sub> 4.4.3 (note 1)	How was test terminated Comments	Meets 4.4.4		
1) T <sub>d</sub> = Test duration in h:min:s Record dielectric strength test on Form A.12 and temperature tests on Form A.18. Record in the comments column for each test whether carried out during or after SINGLE FAULT CONDITION.							
Record in the comm	nents column for ea	_Date:Test equipment No. (Table 2)					

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## 5.1.3.c Mains supply

Marked RATING						NOTE Measurements are required
	F	Phase				only for marked RATINGS
	ŀ	Ηz				
		4				
		N				
		/A				
Test No.	Voltage	Frequency	Current	Power in	Power in	Comments
rest no.	v	Hz	Ι	w	VA	Comments
General com	ments:					
Tested by:		Date:		Test equipm	ent No. (Table	ə 2)

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#### 5.3 Durability of markings

Table A.4.1 – Marking method (note)				
NOTE Where applicable include print method, label material, ink or paint type, fixing method, adhesive and surface to which marking is fixed.				

Table A.4.2 – Agent
---------------------

A (specify agent)

B (specify agent)

C Water

D Isopropyl alcohol

Marking location	Marking method (see Table A.4.1)
Identification (5.1.2)	
Mains supply (5.1.3)	
Fuses (5.1.4)	
Measuring circuit TERMINALS (5.1.5)	
TERMINALS and operating devices (5.1.6)	
Double/reinforced equipment (5.1.7)	
Battery charging (5.1.8)	
Warning markings (5.2)	

Method (Table A.4.1)	Test agent (Table A.4.2)	Remains legible Pass/Fail	Label loose Pass/Fail	Curled edges Pass/Fail	Comments

Tested by:\_\_\_\_\_Date:\_\_\_\_\_Test equipment No. (Table 2)\_\_\_\_

#### Clause 6 – Protection against electric shock – Block diagram of system

POLLUTION DEGREE: \_\_\_\_\_\_INSTALLATION CATEGORY (OVERVOLTAGE CATEGORY):\_\_\_\_\_

Location or	Insulation type	Maximum working voltage	C		E DISTANC te 3)	E	CLEARANCE (note 3)	Test voltage	4
description	(note 1)	(note 2) V	PWB mm	СТІ	Other mm	СТІ	mm	(note 2) V	
BI = E DI = [	insulation: Basic Insulation Double Insulati Protective Impe	ON	RI = REINFORCED INSULATION SI = SUPPLEMENTARY INSULATION						
NOTE 2 Types o Peak impulse test r.m.s.	d.c. peak								
NOTE 3 INSTALLA "Comments".	ATION CATEGORIE	S (OVERVOLTAG	E CATEGO	RIES) OF F	POLLUTION	DEGREES	which differ fro	m these sh	ould be shown under
Tested by:	Tested by:Date:Test equipment No. (Table 2)								

# 6.1.1 Exceptions

#### 6.2 Determination of ACCESSIBLE parts

List of ACCESSIBLE parts

Item	Description	Determination method	Exception under 6.1.1
nem	Description	(note 5)	(note 4)
NOTE 1 Test	I fingers and pins are to be applied w	ithout force unless a force is specified (	see 6.2.1)
		inadequate insulation and high-voltage	
NOTE 3 Part	s are considered to be ACCESSIBLE	if they could be touched in the absen	ce of any covering which is not considered
to provide suita	able insulation (see note to paragrap	h 1 of 6.4).	
	acitor test may be required (see For		nn dianatan ain 4 mm dianatan
NOTE 5 The	determination methods are: visual; r	igid test finger; jointed test finger; pin 3	mm diameter; pin 4 mm diameter.

Tested by:\_\_\_\_\_Date:\_\_\_\_\_Test equipment No. (Table 2)\_\_\_\_\_

#### 6.1.1 Exceptions

11.2 Cleaning 11.3 Spillage

11.4 Overflow

- 6.3.1 Values in NORMAL CONDITION
- 6.6.2 TERMINALS for external circuit
- 6.10.3 Plugs and connections

Item		Voltage			Curre	ent		Capac	itance	10	s test (n	ote)		
(see Form A.6)	V r.m.s	V peak	V d.c.	Test circuit A1/A2/A3	mA r.m.s.	mA peak	mA d.c.	μC	mJ	v	μC	mJ	Comments	
NOTE A5ste	est is spec	ified in 6.	10.3 c).	1	1	1	1	1	1	1	1	1	1	
ested by:			Date		Tes	t equipm	ent No. (	Table 2)						

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ltem	Subclause and fault No.		Voltage		Transient (see note)			Curre	ent		Capaci- tance	
(see Form A.6)	(see Form A.2)	V r.m.s.	V peak	V d.c.	v	S	Test circuit A1/A2/A3	mA r.m.s.	mA peak	mA d.c.	μF (note)	Comments
NOTE Transi	ent voltages must	t be below	the limits	s given fro	m Figure	1 and the	capacitance b	elow the li	mits from I	Figure 2 of	IEC 61010-1.	
Fested by:		Da	ate:		Test	equipme	ent No. (Table	e 2)				

## 6.3.2 Values in SINGLE FAULT CONDITION

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#### Form A.9

#### 6.5.1.1 Cross-sectional area bonding conductors

Conductor location	Cross-sectional area mm <sup>2</sup>	Result Pass/Fail

Tested by:\_\_\_\_\_Date:\_\_\_\_\_Test equipment No. (Table 2)\_\_\_\_\_

#### 6.5.1.2 Bonding impedance of plug connected equipment

Accessible part under test	Test current A	Voltage attained after 1 min V	Calculated resistance (Maximum allowed 0,1 Ω)	Result Pass/Fail

Tested by:\_\_\_\_\_Date:\_\_\_\_\_Test equipment No. (Table 2)\_\_\_\_\_

#### 6.5.1.3 Bonding impedance of PERMANENTLY CONNECTED EQUIPMENT

Test current A	Voltage attained after 1 min (Maximum 10 V) V	Result Pass/Fail
	current	Test after 1 min current (Maximum 10 V)

Tested by:\_\_\_\_\_Date:\_\_\_\_\_Test equipment No. (Table 2)\_\_\_\_\_

#### 6.5.1.4 Indirect bonding for measuring and test equipment

Accessible part under test	Voltage attained	Time for voltage to drop to allowable levels	Result Pass/Fail
a) Voltage limiting device			
	Voltage applied V	Time for device to trip	
b) Voltage-sensitive tripping device			

#### 6.5.3 PROTECTIVE IMPEDANCE

A HIGH INTEGRITY single component									
Component	Location	Comments							
ested by:Date:Test equipment No. (Table 2)									

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 A combination of components

 Component
 Location
 Comments

 Image: Image:

A combination of BASIC INSULATION and a current or voltage limiting device								
Component	Location	Comments						

6.7 CLEARANCES and CREEPAGE DISTANCES

Tested by:\_\_\_\_\_

8 Mechanical resistance to shock, vibration and impact (AM 1 only)

8 Mechanical resistance to shock and impact (AM 2 only)

10.1 Integrity of CLEARANCES and CREEPAGE DISTANCES

Location		sured II - 6.7)	Result		Mechanical tests (note)						l after test uired)	Result	
(see Form A.5)	CREEPAGE DISTANCE	CLEARANCE	Pass/ Fail	Applied force	Rigidity	Impact hammer	Drop and	o 8.1.4 8.4.2	40 °C ambient test	CREEPAGE DISTANCE	CLEARANCE	Pass/ Fail	Comments
	mm	mm		(6.7) N	(8.1)	(8.2)	Normal	Hand-held	(10.1)	mm	mm		
NOTE Refer	Refer to Form A.12 for dielectric strength tests following the above tests.												

\_Date:\_\_\_\_\_Test equipment No. (Table 2)\_\_\_\_\_

Form A.11

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Form A.12

#### 6.8 Dielectric strength tests

Location	Working	Test voltage	Result	Comments
(see Form A.5 and/or fault Form A.2)	voltage V	r.m.s./peak/d.c.	Pass/Fail	(note)
NOTE Describe conditions pr A = Humidity precondition		.8.3)		
A = Humidity precondition B = ENCLOSURE tests (clar C = Resistance to heat of D = After single faults (4.4	non-metallic EN	closures (10.2)		

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Tested by:Date:Test equipment No. (Tabl	ble 2)
---	--------

### 6.10.2.2 Cord anchorage

Location	Mass kg	Pull N	Result Pass/Fail	Torque Nm	Result Pass/Fail	Comments

General comments:

#### Annex G – Test details

Between   and circ	parts cuits	CREEPAGE DISTANCE MM	CLEARANCE mm	Working voltage V	Test voltage r.m.s./peak/d.c. V	Result Pass/Fail	Comments

Tested by:\_\_\_\_\_Date:\_\_\_\_\_Test equipment No. (Table 2)\_\_\_\_\_

Form A.14

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Annex F – Test details F.2.1 Limited circuits

	Open	Open Energy limitation					
Circuit/ Location	circuit voltage r.m.s./d.c. V	Maximum current A	current power		Limited circuit Yes/No	Test to 4.4.3	Comments

General comments:

Tested by:\_\_\_\_\_Date:\_\_\_\_\_Test equipment No. (Table 2)\_\_\_\_\_

#### F.2.2 Unlimited circuit

Location/ Circuit	Operator controlled switch	Overcurrent protection	Over- temperature protection	Comments

General comments:

Annex F - Test details (continued)F.4.2Constructional detailsF.4.3Enclosures

Clause	Requirement	Result Pass/Fail	Comments
F.4.2.1	Connectors comply with IEC standards		
F.4.2.2	Printing wiring boards are flame RATED FV 0 or FV 1		
F.4.2.3	ENCLOSURE surrounds unlimited circuits		
F.4.2.4	Wires comply with IEC standards		
F.4.3.1	High-current devices: - door or - cover and - means to hold door or cover closed or - gap less than limits		
F.4.3.2	Bottom of ENCLOSURES: – no opening or – with Table F.1 and Figure F.1 or – placement of components complies with Figure F.2		
F.4.3.3	Baffle or flame BARRIER: – ENCLOSURE made of metal or – ENCLOSURE made of non-metallic material (FV 0 or FV 1)		

Tested by:\_\_\_\_\_Date:\_\_\_\_\_Test equipment No. (Table 2)\_\_\_\_\_

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#### Annex F - Test details (continued) F.4.3 ENCLOSURES (F4.3.3 test to IEC 60707)

Material tested:					Overall result
Generic name:			Pass/Fail		
Material manufacturer:					
Туре:					
Colour:					
Conditioning details:					
		Sample 1	Sampl	le 2	Sample 3
Thickness of specimen	mm				
Duration of flaming after first application	S				
Duration after flaming plus glowing after second application	S				
Specimen burns to holding clamp	Yes/No				
Cotton ignited	Yes/No				
Sample result	Pass/Fail				

#### 9.2 Temperature tests

- 9.3 Guards
- 9.4 Field wiring TERMINAL boxes

Operating conditions:

Frequency: \_\_\_\_\_ Hz; \_\_\_\_\_Duration: \_\_\_\_\_ h \_\_\_\_ min

Voltage: \_\_\_\_\_ V

Test room ambient: \_\_\_\_\_ °C

Part	t <sub>m</sub> °C	t <sub>c</sub> ℃	t <sub>a</sub> ℃	Result Pass/ Fail	Comments				
NOTE 2 $t_{\rm m}$ = measured tempe $t_{\rm c}$ = corrected maximum	NOTE 1 See also 14.1 with reference to component operating conditions. NOTE 2 $t_m$ = measured temperature $t_c$ = corrected maximum temperature ( $t_m$ °C + 40 °C – test room ambient) $t_a$ = maximum permitted temperature								

Tested by:\_\_\_\_\_Date:\_\_\_\_\_Test equipment No. (Table 2)\_\_\_\_\_

10.2 Resistance to heat of non-metallic enclosures

	Fest method used:       Non-operative treatment       []         Empty ENCLOSURE       []         Operative treatment       []									
Temperature during test:		O°								
ENCLOSURE samples tested we	ere:									
Description	Material	Result Pass/Fail	Comments							
Dielectric strength test (6.8.4)	: V		_r.m.s./peak/d.c.							
Comments:										
Tested by:	Date:	Test equipment No. (Tabl	e 2)							

#### 8 Mechanical resistance to shock and impact

#### 11 Protection against hazards from fluids

Voltage tests can be carried out once after performing the tests of clause 8 and clause 11. However, if voltage tests are carried out separately after each set of tests, two forms can be used.

		Clause	e 8 tests			Clause	11 tests					
Location (see Form	Rigidity	Impact hammer		rop ind 8.4.2)	Cleaning	Spillage	Overflow	IEC 60529	Working voltage	Test voltage	Result Pass/ Fail	Comments
A.5)	(8.1)	(8.2)		(11.6)	(note) V	(note) V						
NOTE Use r.	n.s., d.c or p	eak to indica	te the test vo	bltage used.					<u> </u>	<u> </u>		
			)oto:	-			0)					

Tested by:\_\_\_\_\_ Date:\_\_\_\_\_Test equipment No. (Table 2)\_\_\_\_\_

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# 11.7.2 Leakage and rupture at high pressure

Part	Maximum permissible working pressure MPa	Factor (Figure 4 of IEC 61010-1)	Test pressure MPa	Leakage test Pass/Fail	Burst test Pass/Fail	Comments
Tested by:		Date:		Test equ	ipment No. (Tabl	e 2)

## 11.7.3 Leakage from low-pressure parts

Part	Test pressure MPa	Leakage test Pass/Fail	Comments

Tested by:	Date:	Test equipment No.	(Table 2)
			(

#### 12.2.1 Ionizing radiation

Locations tested	Measured values μSv/h	Result Pass/Fail	Comments

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General comments:

#### 12.5.1 Sound level

# Measured values Calculated maximum sound Location tested dBA pressure level At OPERATOR'S normal position and at bystanders' positions a) b) c) d) e) Comments: Tested by:\_\_\_\_\_Date:\_\_\_\_\_Test equipment No. (Table 2)\_\_\_\_\_

#### 12.5.2 Ultrasonic pressure

Locations tested	Measured values		Comments			
	dB	kHz				
At OPERATOR'S normal position						
At 1 m from the ENCLOSURE						
a)						
b)						
c)						
d)						
е)						
NOTE No limit is specified at present, but a limit of 110 dB above the reference pressure value of 20 µPa is under consideration for applicable frequencies between 20 kHz and 100 kHz.						
Result Pass/Fail						
Comments:						

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Tested by:\_\_\_\_\_Date:\_\_\_\_\_Test equipment No. (Table 2)\_\_\_\_\_

Form A.24

#### 13.2.2 Batteries

Battery load and charging circuit diagram:		
Battery type:		
Battery manufacturer/model/catalogue No.:		
Battery ratings:		
Reverse polarity instalment test – Result (Pass/Fail):		
	Re	sult
Single components failures		s/Fail
Component	Open circuit	Short circuit
Comments:		

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#### Form A.25

#### 4.4.2.4 SINGLE FAULT CONDITIONS, motors 14.2.1 Motor temperatures

Operating conditions:

Frequency: \_\_\_\_\_ Hz; \_\_\_\_\_Duration: \_\_\_\_\_ h \_\_\_\_ min

Voltage: \_\_\_\_\_ V

Test room ambient: \_\_\_\_\_ °C

Motor No. and location	Insulation class (IEC 60085)	t <sub>m</sub> °C	t <sub>c</sub> °C	t <sub>a</sub> °C	Result Pass/Fail	Comments	
NOTE							
t <sub>m</sub> = Measured temperat	NOTE $t_m = Measured temperature$ $t_c = Corrected maximum temperature (t_m °C + 40 °C - test room ambient °C)$						

 $t_a$  = Maximum allowed temperature

14.3 Overtemperature protection devices

Component	Type (note)	Result Pass/Fail	Comments
NOTESR = self-resetting(200 times)NSR = non-self-resetting(10 times)NR = non-resetting(1 time)	es) 3)	1	

General comments:

Form A.26

# 4.4.2.6 Mains transformer

Туре: Ма	anufacturer:					
Tested □ in equipment or □ on bench Optional – Insulation class (IEC 60085) of	the lowest rated wi	nding:				
Winding identification						
Type of protector for winding (note 1)						
Elapsed time						
Current A	Primary					
	Secondary					
Winding temperature °C	Primary					
(note 2)	Secondary					
Tissue paper/cheesecloth OK?	(Pass/Fail)					
Voltage tests (note 3) Primary to secondary	V					
Primary to core	V					
Secondary to secondary	V					
Secondary to core	V					
Result	(Pass/Fail)					
NOTE 1 Primary fuse PF / Secondary fuse SF / Overtemperature protection OP / Impedance protection Z	( )A ( )A ( )°C		I			
NOTE 2 Indicate method of measurement						
TC = with thermocouple R = resistance method						
If resistance method is used, record resi	stance in cold and wa	arm condition under "	Comments".			
NOTE 3 Record the voltage applied and the type NB = no breakdown or B = breakdown.						
Comments:						

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Form	A.28
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#### 4.4.2.6 Mains transformer

14.7.2 Overload tests (	for mains transformers)
-------------------------	-------------------------

Type:	Manufacturer:					
Tested	☐ in equipment or ☐ on bench					
Optional	<ul> <li>Insulation class (IEC 60085) of</li> </ul>	the lowest rated w	winding:			
Winding	identification					
Type of p	protector for winding (note 1)					
Elapsed	time					
Current	А	Primary				
		Secondary				
Winding	temperature °C	Primary				
(note 2)		Secondary				
Tissue p	aper/cheesecloth OK?	(Pass/Fail)				
Voltage	tests (note 3)					
Primary	to secondary	V				
Primary	to core	V				
Seconda	iry to secondary	V				
Seconda	ry to core	V				
Result		(Pass/Fail)				
NOTE 1	Primary fuse     PF /       Secondary fuse     SF /       Overtemperature protection     OP /       Impedance protection     Z	( )A ( )A ( )°C				
NOTE 2	Indicate method of measurement					
	TC = with thermocouple R = resistance method					
	If resistance method is used, record resistance in cold and warm condition under "Comments".					
NOTE 3	E 3 Record the voltage applied and the type of voltage (r.m.s./d.c./peak) and for results use: NB = no breakdown or B = breakdown.					
Commer	nts:					
Tested by	/:Date:	Teste	equipment No. (Table 2)			

#### 16.1 Current measuring circuits

The test is performed with all types and models of current transformers without internal protection, and which are specified by the manufacturer for use with the equipment.

#### a) Current transformers

Type/Model	Rated current A	Test current A	Interrupt Yes/No	Result Pass/Fail	Comments
Tested by:	D	ate:	Test ec	uipment No.	(Table 2)

#### b) Range changing switches

Type/Model	Maximum RATED current of switch	Cycling test Pass/Fail	Comments

# 7.2.101.2 Door motion reversal and stoppage

Description where test applied	Force N	Interlocked Yes/No	Reverse motion Yes/No	Result Pass/Fail

Tested by:\_\_\_\_\_Date:\_\_\_\_\_Test equipment No. (Table 2)\_\_\_\_\_

# 7.2.101.3 Sliding doors

Description where test applied	Speed cm/s	Distance moved cm	Result Pass/Fail		



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Q1	Please report on <b>ONE STANDARD</b> and <b>ONE STANDARD ONLY</b> . Enter the exact number of the standard: ( <i>e.g. 60601-1-1</i> )		Q6	If you ticked NOT AT ALL in Question 5 the reason is: <i>(tick all that apply)</i>	
		)		standard is out of date	
				standard is incomplete	
				standard is too academic	
Q2	Please tell us in what capacity(ies) you bought the standard <i>(tick all that apply).</i> I am the/a:			standard is too superficial	
				title is misleading	
				I made the wrong choice	
	purchasing agent			other	
	librarian				
	researcher				
	design engineer		Q7	Please assess the standard in the	
	safety engineer		<b>u</b> ,	following categories, using	
	testing engineer			the numbers:	
	marketing specialist			(1) unacceptable,	
	other			(2) below average, (3) average,	
				(4) above average,	
Q3	l work for/in/as a:			(5) exceptional,	
Q.)	(tick all that apply)			(6) not applicable	
				timeliness	
	manufacturing			quality of writing	
	consultant			technical contents	
	government			logic of arrangement of contents	
	test/certification facility			tables, charts, graphs, figures	
	public utility			other	
	education				
	military				
	other		Q8	I read/use the: (tick one)	
Q4	This standard will be used for:			French text only	
44	(tick all that apply)			English text only	
				both English and French texts	
	general reference				
	product research				
	product design/development				
	specifications		Q9	Please share any comment on any	
	tenders			aspect of the IEC that you would like us to know:	
	quality assessment			us to know.	
	certification				
	technical documentation				
	thesis				
	manufacturing				
	other				
Q5	This standard meets my needs:				•••••
	(tick one)				
	not at all				
	nearly				
	fairly well				
	exactly				

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