

Shenzhen Well Electric Co., LTD
Mr. Liao Chengwu
-
1-2F, No.227, Hexicun,
Hengkeng Guanlan Town,
Longhuaxinqu,
518110 Shenzhen City
P.R. China

Date : 12/08/2016
Our ref. : QIUPAD 02
Your ref.: L.C.W.

Ref : AK Certificate of Conformity

Type of Equipment : Drug Test Analyzer
Model Designation : See Certificate
Certificate No. : AK 50352982 0001
Report No. : 17050498 001

Dear Mr. Liao Chengwu,

We herewith confirm that a sample of the above mentioned technical equipment has been tested and was found to be in accordance with the relevant requirements.

Enclosed please find your Certificate of Conformity.

We appreciate your kind support and would like to offer our assistance and continuous services in the future.

With kind regards,


Certification Body


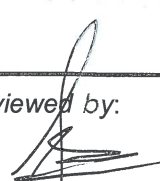
Dipl.-Ing. Univ. S. O. Steinke

Enclosure

证书的详细资料请登陆www.certipedia.com查阅,或拨打我司客服热线800 999 3668 / 400 883 1300咨询

Prüfbericht-Nr.: Test Report No.:	17050498 001	Auftrags-Nr.: Order No.:	164040824	Seite 1 von 48 Page 1 of 48
Kunden-Referenz-Nr.: Client Reference No.:	N/A	Auftragsdatum: Order date:	16.07.2015	
Auftraggeber: Client:	Shenzhen WELL Electric Co., LTD 1-2F, No.227, Hexi Village, Hengkeng Community, Guanlan Sub-District, Longhua New District, Shenzhen City, P.R. China			
Prüfgegenstand: Test item:	Drug Test Analyzer			
Bezeichnung / Typ-Nr.: Identification / Type No.:	WDTP-10			
Auftrags-Inhalt: Order content:	Test report for AK approval			
Prüfgrundlage: Test specification:	EN 61010-1: 2010 EN 61010-2-101:2002			
Wareneingangsdatum: Date of receipt:	16.07.2015			
Prüfmuster-Nr.: Test sample No.:	A000096173-001 ~ 006			
Prüfzeitraum: Testing period:	29.Jan.2016 to 03.Feb.2016			
Ort der Prüfung: Place of testing:	TÜV Rheinland (Shen- zhen) Co., Ltd.			
Prüflaboratorium: Testing laboratory:	TÜV Rheinland (Shen- zhen) Co., Ltd.			
Prüfergebnis*: Test result*:	Pass			



geprüft von / tested by:			kontrolliert von / reviewed by:		
					
11.Aug.2016	Paddy Qiu / Project Manager		11.Aug.2016	Sven-Olaf Steinke /General Manager	
Datum	Name/Stellung	Unterschrift	Datum	Name/Stellung	Unterschrift
Date	Name/Position	Signature	Date	Name/Position	Signature

Sonstiges / Other:
This report is issued for the AK certification approval.
This report consists of:
1) EN 61010-1 report including this cover page (48 pages)
2) Attachment 1: Equipment list (2 pages)
3) Attachment 2: EN 61010-2-101 report (8 pages)
4) Attachment 3: Photo documentation (8 pages)

Zustand des Prüfgegenstandes bei Anlieferung: Condition of the test item at delivery:	Prüfmuster vollständig und unbeschädigt Test item complete and undamaged
* Legende: 1 = sehr gut 2 = gut 3 = befriedigend 4 = ausreichend 5 = mangelhaft P(ass) = entspricht o.g. Prüfgrundlage(n) F(ail) = entspricht nicht o.g. Prüfgrundlage(n) N/A = nicht anwendbar N/T = nicht getestet Legend: 1 = very good 2 = good 3 = satisfactory 4 = sufficient 5 = poor P(ass) = passed a.m. test specification(s) F(ail) = failed a.m. test specification(s) N/A = not applicable N/T = not tested	

Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens.
This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.

TEST REPORT
IEC 61010-1
Safety requirements for electrical equipment for measurement,
control, and laboratory use
Part 1: General requirements

Report Number.....: 17050498 001
Date of issue.....: See cover page.
Total number of pages.....: See cover page.

Applicant's name.....: See cover page.
Address.....: See cover page.

Test specification:

Standard.....: See cover page.
Test procedure.....: See cover page.
Non-standard test method.....: N/A


Test Report Form No.: IEC61010_1H
Test Report Form(s) Originator: VDE Testing and Certification Institute
Master TRF.....: 2011-11

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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.

Test item description.....: Drug Test Analyzer
Trade Mark.....: 
Manufacturer.....: Same as applicant
Model/Type reference.....: WDTP-10
Ratings.....: DC9V,2.5A (via external approved adaptor)
DC 7.4V (via Lithium-Ion rechargeable battery)

Testing procedure and testing location:		
<input checked="" type="checkbox"/>	CB Testing Laboratory:	See cover page.
Testing location/ address..... :		See cover page.
<input type="checkbox"/>	Associated CB Laboratory:	
Testing location/ address..... :		
	Tested by (name + signature) :	See cover page.
	Approved by (name + signature) .. :	See cover page.
<input type="checkbox"/>	Testing procedure: TMP	
Testing location/ address..... :		
	Tested by (name + signature) :	
	Approved by (name + signature) .. :	
<input type="checkbox"/>	Testing procedure: WMT	
Testing location/ address..... :		
	Tested by (name + signature) :	
	Witnessed by (name + signature) . :	
	Approved by (name + signature) .. :	
<input type="checkbox"/>	Testing procedure: SMT	
Testing location/ address..... :		
	Tested by (name + signature) :	
	Approved by (name + signature) .. :	
	Supervised by (name + signature) :	
<input type="checkbox"/>	Testing procedure: RMT	
Testing location/ address..... :		
	Tested by (name + signature) :	
	Approved by (name + signature) .. :	
	Supervised by (name + signature) :	

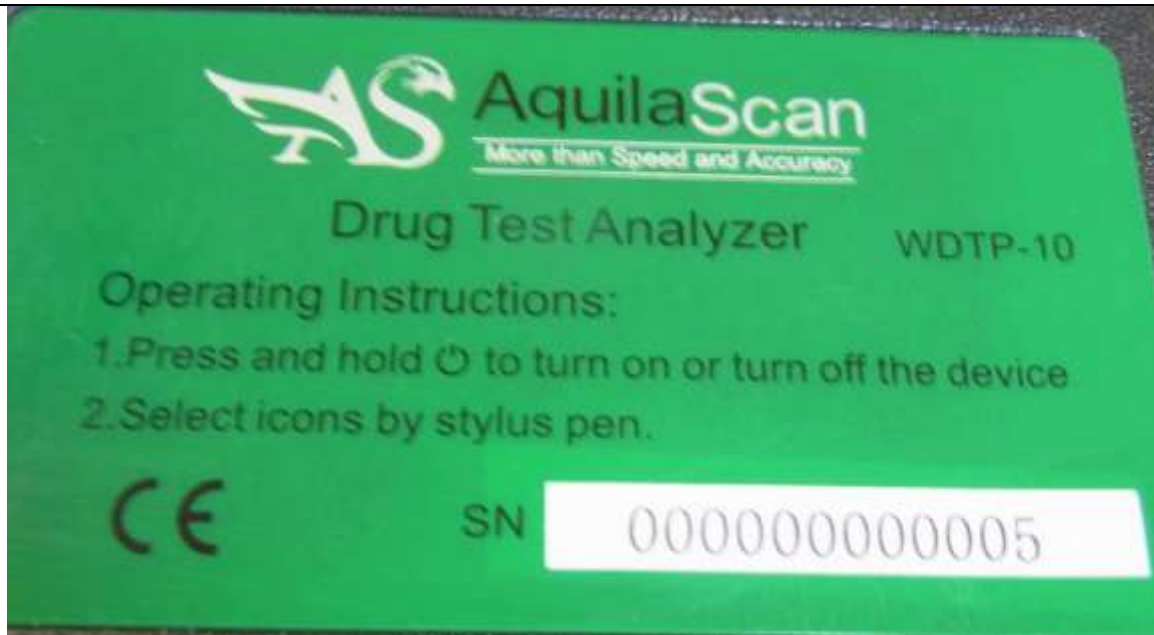
List of Attachments (including a total number of pages in each attachment - Table 1):		
Document No.	Documents included / attached to this report (description)	Page Numbers
See cover page		
Summary of testing: All tests and evaluations are performed according to the user's final configurations in instruction. The results can refer related sub-clause in this report. Test items see below table for detail.		
Test Report History: This report may consist of more than one report and is valid only with additional or previous issued reports:		
Ref. No.	Item	

Tests performed (name of test and test clause):		Testing location: See cover page
Clause	Test Item	
4.4	Testing in SINGLE FAULT CONDITION – Results	
5.3	Durability of markings	
9.4	Limited-energy circuit	
10.	Temperature Measurements	
13.2.2	Batteries	
Summary of compliance with National Differences		
List of countries addressed: NO CENELEC MODIFICATIONS. <input checked="" type="checkbox"/> The product fulfils the requirements of IEC/EN 61010-1:2010.		
Factory(ies): Shenzhen WELL Electric Co., LTD 1-2F, No.227, Hexi Village, Hengkeng Community, Guanlan Sub-District, Longhua New District, Shenzhen City, P.R. China		

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

1. Rating label



2. Warning mark:



Marked near cassette insertion slot.

Test item particulars:

Type of item : measurement equipment

Description of equipment function : Communication

Connection to MAINS supply : Not directly connected to mains.

Overvoltage category : N/A

POLLUTION DEGREE : PD 2

Means of protection..... : N/A

Environmental conditions..... : Normal

For use in wet locations : No

Equipment mobility..... : Portable

Operating conditions : Continuous

Overall size of equipment (W x D x H) : 56.4mm x 209mm x 90mm

Mass of equipment (kg) : 0.45

Marked degree of protection to IEC 60529 : IP20

Possible test case verdicts:

- Test case does not apply to the test object..... : N/A
- Test object does meet the requirement..... : P (Pass)
- Test object does not meet the requirement : F (Fail)

Testing:

Date of receipt of test item : See cover page.

Date (s) of performance of tests : See cover page.

General remarks:

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 testing laboratory.
"(see ENCLOSURE #)" refers to additional information appended to the report.
"(see Form A.xx)" refers to a table appended to the report.
Bottom lines for measurement tables Form A.xx are optional if used as record.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Manufacturer's Declaration per sub-clause 6.2.5 of IEC 60335-1:

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided..... : ☐ Yes ☒ Not applicable

When differences exist; they shall be identified in the General product information section.

General product information:

This product is measurement equipment for drug test via saliva analysis.

EUT can be supplied by built-in Li-ion rechargeable battery or external approved AC/DC adapter which tested to comply with L.P.S. (see appended table 1 for details)

separate evaluated the product according the standard of EN 61010-2-101:2002 in attachment 2.

The operation temperature is evaluated up to 40°C.

The product mainly consists of:

- 1) Plastic enclosure
- 2) Main board
- 3) External approved adaptor
- 4) Built-in rechargeable battery
- 5) LCD panel board
- 6) Printing module

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict

4.4	Testing in SINGLE FAULT CONDITIONS		P
4.4.1	Fault tests	(see Form A.1)	P
4.4.2	Application of SINGLE FAULT CONDITIONS		P
4.4.2.1	SINGLE FAULT CONDITIONS not covered by 4.4.2.2 to 4.4.2.14	(see Form A.1)	—
4.4.2.2	PROTECTIVE IMPEDANCE		N/A
4.4.2.3	PROTECTIVE CONDUCTOR		N/A
4.4.2.4	Equipment or parts for short-term or intermittent operation		N/A
4.4.2.5	Motors		N/A
	– stopped while fully energized		N/A
	– prevented from starting		N/A
	– one phase interrupted (multi-phase)		N/A
4.4.2.6	Capacitors		N/A
4.4.2.7	MAINS transformers		N/A
4.4.2.7.2	Short circuit		N/A
4.4.2.7.3	Overload		N/A
4.4.2.8	Outputs		P
4.4.2.9	Equipment for more than one supply		N/A
4.4.2.10	Cooling	(see Form A.26A)	N/A
	– air holes closed		N/A
	– fans stopped		N/A
	– coolant stopped	No coolant used	N/A
	– loss of cooling liquid	No cooling liquid	N/A
4.4.2.11	Heating devices	No heating device	N/A
	– timer overridden		N/A
	– temperature controller overridden		N/A
4.4.2.12	Insulation between circuits and parts		P
4.4.2.13	Interlocks	No interlocks	N/A
4.4.2.14	Voltage selectors		N/A
4.4.3	Duration of tests	(see Form A.1)	—
4.4.4	Conformity after application of fault conditions	(see Forms A.1; A.6, A.18)	P

5	MARKING AND DOCUMENTATION		P
5.1.1	Required equipment markings		P
	- Visible from the exterior; or	Rating label is marked on apparatus enclosure.	P
	- Visible after removing cover or opening door	No such cover	N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	- Visible after removal from a rack or panel	No such cover	N/A
	Not put on parts which can be removed by an operator	No parts could remove by an operator	P
	Letter symbols (IEC 60027) used		P
	Graphic symbols (IEC 61010-1: Table 1) used		P
5.1.2	Identification		—
	Equipment is identified by:		P
	1) Manufacturer's or supplier's name or trademark	Manufacturer marked.	P
	2) Model number, name or other means	See marking label	P
	Manufacturing location identified	Only one manufacturing location	N/A
5.1.3	MAINS supply	Not directly connected to mains	N/A
	Equipment is marked as follows:		N/A
	a) Nature of supply:		—
	1) a.c. RATED MAINS frequency or range of frequencies		N/A
	2) d.c. with symbol 1		N/A
	b) RATED supply voltage(s) or range	DC 9V (via external approved adaptor) DC 7.4V (via Lithium-Ion rechargeable battery)	N/A
	c) Max. RATED power (W or VA) or input current ... :		N/A
	The marked value not less than 90 % of the maximum value		N/A
	If more than one voltage range:		—
	Separate values marked; or		N/A
	Values differ by less than 20 %		N/A
	d) OPERATOR-set for different RATED supply voltages:	No such operator-set	—
	Indicates the equipment set voltage		N/A
	Portable equipment indication is visible from the exterior		N/A
	Changing the setting changes the indication		N/A
	e) Accessory MAINS socket-outlets accepting standard MAINS plugs are marked:	No such socket-outlets used	N/A
	With the voltage if it is different from the MAINS supply voltage		N/A
	For use only with specific equipment		N/A
	If not marked for specific equipment it is marked with:		N/A
	The maximum rated current or power; or		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Symbol 14 with full details in the documentation		N/A
5.1.4	Fuses		N/A
	Operator replaceable fuse marking (see also 5.4.5)		N/A
5.1.5	TERMINALS, connections and operating devices		P
5.1.5.1	General		P
	Where necessary for safety, indication of purpose of TERMINALS, connectors, controls and indicators marked		P
	If insufficient space, symbol 14 used		N/A
	Push-buttons and actuators of emergency stop devices and indicators:	No such push-buttons and actuators	—
	used only to indicate a warning of danger or		N/A
	the need for urgent action		N/A
	coloured red		N/A
	coded as specified in IEC 60073		N/A
	Supplementary means of coding provided, if meaning of colour relates (see IEC 60073):		N/A
	to safety of persons; or		N/A
	safety of the environment		N/A
5.1.5.2	TERMINALS		N/A
	MAINS supply TERMINAL identified		N/A
	Other TERMINAL marking:		N/A
	a) FUNCTIONAL EARTH TERMINALS (symbol 5 used)		N/A
	b) PROTECTIVE CONDUCTOR TERMINALS:		N/A
	Symbol 6 is placed close to or on the TERMINAL; or		N/A
	Part of appliance inlet		N/A
	c) TERMINALS of control circuits (symbol 7 used)		N/A
	d) HAZARDOUS LIVE TERMINALS supplied from the interior	No such terminals	N/A
	Standard MAINS socket outlet; or		N/A
	RATINGS marked; or		N/A
	Symbol 14 used		N/A
5.1.6	Switches and circuit breakers		N/A
	If disconnecting device, off position clearly marked		N/A
	If push-button used as power supply switch:		N/A
	Symbol 9 and 15 used for on-position		N/A
	Symbol 10 and 16 used for off-position		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Pair of symbols 9, 15 and 10, 16 close together		N/A
5.1.7	Equipment protected by DOUBLE INSULATION or REINFORCED INSULATION		N/A
	Protected throughout (symbol 11 used)	Class III equipment	N/A
	Only partially protected (symbol 11 not used)		N/A
5.1.8	Field-wiring TERMINAL boxes	No such terminal boxed used	N/A
	If TERMINAL or ENCLOSURE exceeds 60 °C:		N/A
	Cable temperature RATING marked :		N/A
	Marking visible before and during connection or beside TERMINAL		N/A
5.2	Warning markings	No warning markings.	N/A
	Visible when ready for NORMAL USE		N/A
	Are near or on applicable parts		N/A
	Symbols and text correct dimensions and colour:		—
	a) symbols min 2,75 mm and text 1,5 mm high and contrasting in colour with background		N/A
	b) symbols and text moulded, stamped or engraved in material min. 2,0 mm high and		N/A
	0,5 mm depth or raised if not contrasting in colour		N/A
	If necessary marked with symbol 14		N/A
	Statement to isolate or disconnect if access by using a tool to HAZARDOUS LIVE parts is permitted		N/A
5.3	Durability of markings		P
	The required markings remain clear and legible in NORMAL USE	(see Form A.3)	P
5.4	Documentation		P
5.4.1	General		P
	Equipment is accompanied by documentation for safety purposes for OPERATOR or RESPONSIBLE BODY		P
	Safety documentation for service personnel authorized by the manufacturer		P
	Documentation necessary for safe operation is provided in printed media or	Printed user manual provided	P
	in electronic media if available at any time		N/A
	Documentation includes:		—
	a) intended use	Specified in user manual	P
	b) technical specification		P
	c) name and address of manufacturer or supplier	Specified in user manual	P
	d) information specified in 5.4.2 to 5.4.6		P

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	e) information to mitigate residual RISK (see also subclause 17)		N/A
	f) accessories for safe operation of the equipment specified	Specified in user manual	P
	g) guidance provided to check correct function of the equipment, if incorrect reading may cause a HAZARD from harmful or corrosive substances of HAZARDOUS live parts	Specified in user manual	P
	h) instructions for lifting and carrying	Specified in user manual	P
	Warning statements and a clear explanation of warning symbols:		—
	Provided in the documentation; or	Explanation clearly in user manual	P
	Information is marked on the equipment		N/A
5.4.2	Equipment ratings		P
	Documentation includes:		—
	a) Supply voltage or voltage range	DC 9V (via external approved adaptor) DC 7.4V (via Lithium-Ion rechargeable battery)	P
	Frequency or frequency range	DC supply	N/A
	Power or current rating.....	2.5A (via external approved adaptor)	P
	b) Description of all input and output connections in accordance to 6.6.1 a)		N/A
	c) RATING of insulation of external circuits in accordance to 6.6.1 b)	Specified in user manual	P
	d) Statement of the range of environmental conditions (see 1.4)	Specified in user manual	P
	e) Degree of protection (IEC 60529)	IP20	P
	f) if impact rating less than 5 J:	Not specified request	N/A
	IK code in accordance to IEC 62262 marked or		N/A
	symbol 14 of table 1 marked, with		N/A
	RATED energy level and test method stated		N/A
5.4.3	Equipment installation		P
	Documentation includes instructions for:		P
	a) assembly, location and mounting requirements	Specified in user manual	P
	b) protective earthing		N/A
	c) connections to supply	Specified in user manual	P
	d) PERMANENTLY CONNECTED EQUIPMENT:	Not permanently connected equipment	N/A
	1) Supply wiring requirements		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	2) If external switch or circuit-breaker, requirements and location recommendation		N/A
	e) ventilation requirements		P
	f) special services (e. g. air, cooling liquid)		N/A
	g) instructions relating to sound level		N/A
5.4.4	Equipment operation		P
	Instructions for use include:		P
	a) identification and description of operating controls		P
	b) positioning for disconnection		N/A
	c) instructions for interconnection		N/A
	d) specification of intermittent operation limits	Continuous operation	N/A
	e) explanation of symbols used		P
	f) replacement of consumable materials	No consumable materials	N/A
	g) cleaning and decontamination		P
	h) listing of any poisonous or injurious gases and quantities	No poisonous or injurious gases	N/A
	i) RISK reduction procedures relating to flammable liquids (see 9.5)		N/A
	j) RISK reduction procedures relating burn from surfaces permitted to exceed limits of 10.1		N/A
	Additional precautions for IEC 60950 conforming equipment in regard to moistures and liquids		N/A
	A statement about protection impairment if used in a manner not specified by the manufacturer		N/A
5.4.5	Equipment maintenance and Service		P
	Instructions for RESPONSIBLE BODY include:		—
	Instructions sufficient in detail permitting safe maintenance and inspection and continued safety:		P
	Instruction against the use of detachable MAINS supply cord with inadequate rating		N/A
	Specific battery type of user replaceable batteries	See user manual	P
	Any manufacturer specified parts		P
	Rating and characteristics of fuses		N/A
	Instructions include following subjects permitting safe servicing and continued safety:		N/A
	a) product specific RISKS may affect service personnel		N/A
	b) protective measures for these RISKS		N/A
	c) verification of the safe state after repair		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict

5.4.6	Integration into systems or effects resulting from special conditions		N/A
	Aspects described in documentation		N/A

6	PROTECTION AGAINST ELECTRIC SHOCK		N/A
6.1	General	No hazardous live parts inside equipment.	N/A
6.1.1	Requirements		—
	Protection against electric shock maintained in NORMAL CONDITION and SINGLE FAULT CONDITION		N/A
	ACCESSIBLE parts not HAZARDOUS LIVE		N/A
	Voltage, current, charge or energy below the limits in NORMAL CONDITION and in SINGLE FAULT CONDITION between:		—
	ACCESSIBLE parts and earth		N/A
	two ACCESSIBLE parts on same piece of the equipment within a distance of 1,8 m		N/A
	Conformity is checked by the determination of 6.2 and 6.3 followed by the tests of 6.4 to 6.11		N/A
6.1.2	Exceptions		N/A
	Following HAZARDOUS LIVE parts may be ACCESSIBLE to an OPERATOR:		N/A
	a) parts of lamps and lamp sockets after lamp removal		N/A
	b) parts to be replaced by OPERATOR only by the use of tool and warning marking		N/A
	Those parts not HAZARDOUS LIVE 10 s after interruption of supply		N/A
	Capacitance test if charge is received from internal capacitor		N/A
6.2	Determination of ACCESSIBLE parts	(see Form A.5)	N/A
6.2.1	General		N/A
	Unless obviously determination of ACCESSIBLE parts as specified in 6.2.2 to 6.2.4		N/A
6.2.2	Examination		N/A
	- with jointed test finger (as specified B.2)		N/A
	- with rigid test finger (as specified B.1) and a force of 10 N		N/A
6.2.3	Openings above parts that are HAZARDOUS LIVE		N/A
	- test pin with length of 100 mm and 4 mm in diameter applied		N/A
6.2.4	Openings for pre-set controls		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	- test pin with length of 100 mm and 3 mm in diameter applied		N/A
6.3	Limit values for ACCESSIBLE parts		N/A
6.3.1	Levels in NORMAL CONDITION		N/A
	a) Voltage limits less than 33 V r.m.s. and 46,7 V peak or 70 V d.c.		N/A
	for WET LOCATIONS voltage limits less than 16 V r.m.s. and 22,6 V peak or 35 V d.c.		N/A
	Voltages are not HAZARDOUS LIVE the levels of:		—
	b) Current less than 0,5 mA r.m.s. for sinusoidal, 0,7 mA peak non sinusoidal or mixed frequencies or 2 mA d.c. when measured with measuring circuit A.1 or A.2 if less than 100 Hz		N/A
	for WET LOCATIONS measuring circuit A.4 used		N/A
	70 mA r.m.s. when measured with circuit A.3 for higher frequencies		N/A
	or		N/A
	c) Levels of capacitive charge or energy less:		N/A
	1) 45 μ C for voltages up to 15 kV peak or d.c. or line A of Figure 3		N/A
	2) 350 mJ stored energy for voltages above 15 kV peak or d.c.		N/A
6.3.2	Levels in SINGLE FAULT CONDITION		N/A
	a) Voltage limits less than 55 V r.m.s. and 78 V peak or 140 V d.c.		N/A
	for WET LOCATIONS voltage limits less than 33 V r.m.s. and 46,7 V peak or 70 V d.c.		N/A
	Voltages are not HAZARDOUS LIVE the levels of:		—
	b) Current less than 3,5 mA r.m.s. for sinusoidal, 5 mA peak non sinusoidal or mixed frequencies or 15 mA d.c. when measured with measuring circuit A.1 or A.2 if less than 100 Hz		N/A
	for WET LOCATIONS measuring circuit A.4 used		N/A
	500 mA r.m.s. when measured with circuit A.3 for higher frequencies		N/A
	or		N/A
	c) Levels of capacitive charge or energy less line B of Figure 3		N/A
6.4	Primary means of protection		N/A
6.4.1	ACCESSIBLE parts prevented from being HAZARDOUS LIVE by one or more of following means:		N/A
	a) ENCLOSURES or PROTECTIVE BARRIERS (see 6.4.2)		N/A
	b) BASIC INSULATION (see 6.4.3)		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) Impedance (see 6.4.4)		N/A
6.4.2	ENCLOSURES or PROTECTIVE BARRIERS		N/A
	- meet rigidity requirements of 8.1		N/A
	- meet requirements for BASIC INSULATION, if protection is provided by insulation		N/A
	- meet requirements of 6.7 for CREEPAGE and CLEARANCES between ACCESSIBLE parts and HAZARDOUS live parts, if protection is provided by limited access		N/A
6.4.3	BASIC INSULATION		N/A
	- meet CLEARANCE, CREEPAGE DISTANCE and solid insulation requirements of 6.7		N/A
6.4.4	Impedance		N/A
	Impedance used as primary means of protection meets all of following requirements:		—
	a) limits current or voltage to level of 6.3.2		N/A
	b) RATED for maximum WORKING VOLTAGE and the amount of power it will dissipate		N/A
	c) CLEARANCE, CREEPAGE DISTANCE between terminations of the impedance meet requirements of BASIC INSULATION of 6.7		N/A
6.5	Additional means of protection in case of SINGLE FAULT CONDITION		N/A
6.5.1	ACCESSIBLE parts are prevented from becoming HAZARDOUS live by the primary means of protection and supplemented by one of:		N/A
	a) PROTECTIVE BONDING (see 6.5.2)		N/A
	b) SUPPLEMENTARY INSULATION (see 6.5.3)		N/A
	c) automatic disconnection of the supply (see 6.5.5)		N/A
	d) current- or voltage-limiting device (see 6.5.6)		N/A
	Alternatively one of the single means of protection is used:		N/A
	e) REINFORCED INSULATION (see 6.5.3)		N/A
	f) PROTECTIVE IMPEDANCE (see 6.5.4)		N/A
6.5.2	PROTECTIVE BONDING		N/A
6.5.2.1	ACCESSIBLE conductive parts, may become HAZARDOUS LIVE in SINGLE FAULT CONDITION:		N/A
	Bonded to the PROTECTIVE CONDUCTOR TERMINAL; or		N/A
	Separated by conductive screen or barrier bonded to PROTECTIVE CONDUCTOR TERMINAL		N/A
6.5.2.2	Integrity of PROTECTIVE BONDING		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	a) PROTECTIVE BONDING consists of directly connected structural parts or discrete conductors or both; and withstands thermal and dynamic stresses		N/A
	b) Soldered connections:		N/A
	Independently secured against loosening		N/A
	Not used for other purposes		N/A
	c) Screw connections are secured		N/A
	d) PROTECTIVE BONDING not interrupted; or		N/A
	exempted as removable part carries MAINS SUPPLY input connection		N/A
	e) Any movable PROTECTIVE BONDING connection specifically designed, and meets 6.5.2.4		N/A
	f) No external metal braid of cables used (not regarded as PROTECTIVE BONDING)		N/A
	g) IF MAINS SUPPLY passes through:		N/A
	Means provided for passing protective conductor;		N/A
	Impedance meets 6.5.2.4		N/A
	h) Protective conductors bare or insulated, if insulated, green/yellow		N/A
	Exceptions:		N/A
	1) earthing braids;		N/A
	2) internal protective conductors etc.;		N/A
	Green/yellow not used for other purposes		N/A
	TERMINAL suitable for connection of a PROTECTIVE CONDUCTOR, and meets 6.5.2.3		N/A
6.5.2.3	PROTECTIVE CONDUCTOR TERMINAL		N/A
	a) Contact surfaces are metal		N/A
	b) Appliance inlet used		N/A
	c) For rewirable cords and PERMANENTLY CONNECTED EQUIPMENT, PROTECTIVE CONDUCTOR TERMINAL is close to MAINS supply TERMINALS		N/A
	d) If no MAINS supply is required, any PROTECTIVE CONDUCTOR TERMINAL:		N/A
	Is near terminals of circuit for which protective earthing is necessary		N/A
	External if other terminals external		N/A
	e) Equivalent current-carrying capacity to MAINS supply TERMINALS		N/A
	f) If plug-in, makes first and breaks last		N/A
	g) If also used for other bonding purposes, PROTECTIVE CONDUCTOR:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Applied first;		N/A
	Secured independently;		N/A
	Unlikely to be removed by servicing		N/A
	h) PROTECTIVE CONDUCTOR of measuring circuit:		N/A
	1) Current RATING equivalent to measuring circuit TERMINAL;		N/A
	2) PROTECTIVE BONDING:		N/A
	Not interrupted; or		N/A
	i) FUNCTIONAL EARTH TERMINALS allow independent connection		N/A
	j) IF A BINDING SCREW USED FOR PROTECTIVE CONDUCTOR TERMINAL:		N/A
	Suitable size for bond wire		N/A
	Not smaller than M 4		N/A
	At least 3 turns of screw engaged		N/A
	Passes tightening torque test		N/A
	k) Contact pressure not capable being reduced by deformation of materials		N/A
6.5.2.4	Impedance of PROTECTIVE BONDING of plug-connected equipment		N/A
	Impedance between PROTECTIVE CONDUCTOR TERMINAL and each ACCESSIBLE part where PROTECTIVE BONDING is specified, is:		—
	less than 0,1 Ohm; or		N/A
	less than 0,2 Ohm if equipment is provided with non detachable cord		N/A
6.5.2.5	Bonding impedance of PERMANENTLY CONNECTED EQUIPMENT		N/A
6.5.2.6	Transformer PROTECTIVE BONDING screen		N/A
	Transformer provided with screen for PROTECTIVE BONDING:		N/A
	screen bonding consists of directly connected structural parts or discrete conductors or both; and withstands thermal and dynamic stresses (see 6.5.2.2 a)		N/A
	screen bonding with soldered connection (see 6.5.2.2 b) is:		N/A
	- Independently secured against loosening		N/A
	- Not used for other purposes		N/A
6.5.3	SUPPLEMENTARY and REINFORCED INSULATION		N/A
	Meet CLEARANCE, CREEPAGE DISTANCE and solid insulation requirements of 6.7		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
6.5.4	PROTECTIVE IMPEDANCE		N/A
	Limits current or voltage to level of 6.3.1 in NORMAL and to level of 6.3.2 in SINGLE FAULT CONDITION		N/A
	CLEARANCE, CREEPAGE DISTANCE between terminations of the impedance meet requirements of DOUBLE OR REINFORCED INSULATION of 6.7		N/A
	The PROTECTIVE IMPEDANCE consists of one or more of the following:		—
	a) appropriate single component suitable for safety and reliability for protection, it is:		N/A
	1) RATED twice the maximum WORKING VOLTAGE		N/A
	2) resistor RATED for twice the power dissipation for maximum WORKING VOLTAGE		N/A
	b) combination of components		N/A
	Single electronic device not used as PROTECTIVE IMPEDANCE		N/A
6.5.5	Automatic disconnection of the supply	No such connection	N/A
	a) RATED to disconnect the load within time specified in Figure 2		N/A
	b) RATED for the maximum load conditions of the equipment		N/A
6.5.6	Current- or voltage-limiting devices		N/A
	Device complies with all of:		N/A
	a) RATED to limit the current or voltage to the level of 6.3.2		N/A
	b) RATED for the maximum WORKING VOLTAGE; and		N/A
	RATED for the maximum operational current if applicable		N/A
	c) CLEARANCE, CREEPAGE DISTANCE between terminations of the impedance meet requirements of SUPPLEMENTARY INSULATION of 6.7		N/A
6.6	Connections to external circuits		N/A
6.6.1	Connections do not cause ACCESSIBLE parts of the following to become HAZARDOUS LIVE in NORMAL CONDITION or SINGLE FAULT CONDITION:		N/A
	- the external circuits		N/A
	- the equipment		N/A
	Protection achieved by separation of circuits; or		N/A
	short circuit of separation does not cause a HAZARD		N/A
	Instructions or markings for each terminal include:		N/A
	a) RATED conditions for TERMINAL		N/A
	b) Required RATING of external circuit insulation		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
6.6.2	TERMINALS for external circuits		N/A
	TERMINALS which receive a charge from an internal capacitor are not HAZARDOUS LIVE after 10 s of interrupting supply connection		N/A
6.6.3	Circuits with terminals which are HAZARDOUS LIVE	No hazardous live terminals	N/A
	These circuits are:		N/A
	Not connected to ACCESSIBLE conductive parts; or		N/A
	Connected to ACCESSIBLE conductive parts, but are not MAINS CIRCUITS and have one TERMINAL contact at earth potential		N/A
	No ACCESSIBLE conductive parts are HAZARDOUS LIVE		N/A
6.6.4	ACCESSIBLE terminals for stranded conductors	No such terminals	N/A
	No RISK of accidental contact because:		N/A
	Located or shielded		N/A
	Self-evident or marked whether or not connected to ACCESSIBLE conductive parts		N/A
	ACCESSIBLE TERMINALS will not work loose		N/A
6.7	Insulation requirements		N/A
6.7.1	The nature of insulation		N/A
6.7.1.1	Insulation between ACCESSIBLE parts or between separate circuits consist of CLEARANCES, CREEPAGE DISTANCES and solid insulation if provided as protection against a HAZARD		N/A
6.7.1.2	CLEARANCES		N/A
	Required CLEARANCES reflecting factors of 6.7.1.1		N/A
	Equipment rated for operating altitude greater than 2000 m correction factor of Table 3 of 61010-1 applied		N/A
6.7.1.3	CREEPAGE DISTANCES		N/A
	Required CREEPAGE DISTANCES reflecting factors of 6.7.1.1 a) to d)		N/A
	CTI material group reflected by requirements		N/A
	CTI test performed		N/A
6.7.1.4	Solid insulation		N/A
	Required solid insulation reflecting factors of 6.7.1.1 a) to d)		N/A
6.7.1.5	Requirements for insulation according to type of circuit		N/A
	a) 6.7.2 MAINS circuits of OVERVOLTAGE CATEGORY II up to nominal supply voltage of 300 V		N/A
	b) 6.7.3 secondary circuits separated from circuits defined in a) by transformer		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	c) K.1 MAINS circuits of OVERVOLTAGE CATEGORY III and IV or OVERVOLTAGE CATEGORY II over 300 V		N/A
	d) K.2 secondary circuits separated from circuits defined in c) by transformer		N/A
	e) K.3 circuits having one or more of:		N/A
	1) maximum TRANSIENT OVERVOLTAGE is limited to known level below the level of MAINS CIRCUIT		N/A
	2) maximum TRANSIENT OVERVOLTAGE above the level of MAINS CIRCUIT		N/A
	3) WORKING VOLTAGE is the sum of more than one circuit or a mixed voltage		N/A
	4) WORKING VOLTAGE includes recurring peak voltage, may include non-sinusoidal or non-periodic waveform		N/A
	5) WORKING VOLTAGE with a frequency above 30 kHz		N/A
6.7.2	Insulation for MAINS CIRCUITS of OVERVOLTAGE CATEGORY II with a nominal supply voltage up to 300 V		N/A
6.7.2.1	CLEARANCES and CREEPAGE DISTANCES		N/A
	Values for MAINS CIRCUITS of table 4 are met		N/A
	Coatings to achieve reduction to POLLUTION DEGREE 1 comply with requirements of Annex H		N/A
6.7.2.2	Solid insulation		N/A
6.7.2.2.1	Withstands electrical and mechanical stresses in normal use and all RATED environmental conditions of 1.4		N/A
	Equipment passed voltage tests of 6.8.3 with values of Table 5		N/A
	Complies as applicable:		N/A
	a) ENCLOSURE or PROTECTIVE BARRIER of Clause 8		N/A
	b) moulded and potted parts requirements of 6.7.2.2.2		N/A
	c) inner layers of printed wiring boards requirements of 6.7.2.2.3		N/A
	d) thin-film insulation requirements of 6.7.2.2.4		N/A
6.7.2.2.2	Moulded and potted parts		N/A
	Conductors between same two layers are separated by at least 0,4 mm after moulding is completed		N/A
6.7.2.2.3	Inner insulating layers of printed wiring boards	No such insulation	N/A
	Separated by at least 0,4 mm between same two layers		N/A
	REINFORCED INSULATION have adequate electric strength; one of following methods used:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	a) thickness of insulation is at least 0,4 mm		N/A
	b) insulation is assembled of minimum two separate layers, each RATED for test voltage of Table 5 for BASIC INSULATION		N/A
	c) insulation is assembled of minimum two separate layers, where the combination is rated for test voltage of Table 5 for REINFORCED INSULATION		N/A
6.7.2.2.4	Thin-film insulation		N/A
	Conductors between same two layers are separated by applicable CLEARANCES and CREEPAGE DISTANCE of 6.7.2.1		N/A
	REINFORCED INSULATION have adequate electric strength; one of following methods used:		N/A
	a) thickness through the insulation at least 0,4 mm		N/A
	b) insulation is assembled of min two separate layers, each RATED for test voltage of Table 5 for BASIC INSULATION		N/A
	c) insulation is assembled of min three separate layers, where the combination of two layers passed voltage tests of 6.8.3 with values of Table 5 for REINFORCED INSULATION		N/A
6.7.3	Insulation for secondary circuits derived from MAINS CIRCUITS of OVERVOLTAGE CATEGORY II up to 300 V		N/A
6.7.3.1	Secondary circuits where separation from MAINS CIRCUITS is achieved by a transformer providing:		N/A
	- REINFORCED INSULATION		N/A
	- DOUBLE INSULATION		N/A
	- screen connected to the PROTECTIVE CONDUCTOR TERMINAL		N/A
6.7.3.2	CLEARANCES		N/A
	a) meet the values of Table 6 for BASIC INSULATION and SUPPLEMENTARY INSULATION; or		N/A
	twice the values of Table 6 for REINFORCED INSULATION		N/A
	or		—
	b) pass the voltage tests of 6.8 with values of Table 6; with following adjustments:		N/A
	1) values for REINFORCED INSULATION are 1,6 times the values for BASIC INSULATION		N/A
	2) if operating altitude is greater than 2000 m values of CLEARANCES multiplied with factor of Table 3		N/A
	3) minimum CLEARANCE is 0,2 mm for POLLUTION DEGREE 2 and 0,8 mm for POLLUTION DEGREE 3		N/A
6.7.3.3	CREEPAGE DISTANCES		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Based on WORKING VOLTAGE meets the values of Table 7 for BASIC and SUPPLEMENTARY INSULATION		N/A
	Values for REINFORCED INSULATION are twice the values of BASIC INSULATION		N/A
	Coatings to achieve reduction to POLLUTION DEGREE 1 comply with requirements of Annex H		N/A
6.7.3.4	Solid insulation		N/A
6.7.3.4.1	Withstands electrical and mechanical stresses in normal use and all RATED environmental conditions of 1.4		N/A
	a) Equipment passed voltage test of 6.8.3.1 for 5 s with VALUES of Table 6 for BASIC and SUPPLEMENTARY INSULATION		N/A
	values for REINFORCED INSULATION are 1,6 times the values of BASIC INSULATION		N/A
	b) if WORKING VOLTAGE exceeds 300 V, equipment passed voltage test of 6.8.3.1 for 1 min with a test voltage of 1,5 times working voltage for BASIC or SUPPLEMENTARY INSULATION		N/A
	value for REINFORCED INSULATION are twice the WORKING VOLTAGE		N/A
	Complies as applicable:		N/A
	1) ENCLOSURE or PROTECTIVE BARRIER of Clause 8		N/A
	2) moulded and potted parts requirements of 6.7.3.4.2		N/A
	3) inner layers of printed wiring boards requirements of 6.7.3.4.3		N/A
	4) thin-film insulation requirements of 6.7.3.4.4		N/A
6.7.3.4.2	Moulded and potted parts		N/A
	Conductors between same two layers are separated by applicable distances of Table 8		N/A
6.7.3.4.3	Inner insulation layers of printed wiring boards		N/A
	Separated by at least by applicable distances of Table 8 between same two layers		N/A
	REINFORCED INSULATION have adequate electric strength; one of following methods used:		N/A
	a) thickness at least applicable distance of Table 8		N/A
	b) insulation is assembled of minimum two separate layers, each RATED for test voltage of Table 6 for BASIC INSULATION		N/A
	c) insulation is assembled of min two separate layers, where the combination is RATED for 1,6 times the test voltage of Table 6		N/A
6.7.3.4.4	Thin-film insulation		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Conductors between same two layers are separated by applicable CLEARANCES and CREEPAGE DISTANCE of 6.7.3.2 and 6.7.3.3		N/A
	REINFORCED INSULATION have adequate electric strength; one of following methods used:		N/A
	a) thickness at least applicable distance of Table 8		N/A
	b) insulation is assembled of min two separate layers, each RATED for test voltage of Table 6 for BASIC INSULATION		N/A
	c) insulation is assembled of min three separate layers, where the combination of two layers passed voltage tests with 1,6 time values of Table 6:		N/A
	a.c. test of 6.8.3.1; or		N/A
	d.c. test of 6.8.3.2 for circuits stressed only by d.c. voltages		N/A
6.8	Procedure for dielectric strength tests		N/A
6.9	Constructional requirements for protection against electric shock		N/A
6.9.1	If a failure could cause a HAZARD:		N/A
	a) Security of wiring connections		N/A
	b) Screws securing removable covers	No such screws	N/A
	c) Accidental loosening		N/A
	d) CLEARANCES and CREEPAGE DISTANCES not reduced below the values of basic insulation by loosening of parts or wires		N/A
6.9.2	Insulating materials		N/A
	Material not to be used for safety relevant insulation:		N/A
	a) Easily damaged materials not used	No such materials used	N/A
	b) Non-impregnated hygroscopic materials not used	No such materials used	N/A
6.9.3	Colour coding		N/A
	Green-and-yellow insulation shall not be used except:		N/A
	a) protective earth conductors;		N/A
	b) PROTECTIVE BONDING conductors;		N/A
	c) potential equalization conductors;		N/A
	d) functional earth conductors		N/A
6.10	Connection to MAINS supply source and connections between parts of equipment		N/A
6.10.1	MAINS supply cords		N/A
	RATED for maximum equipment current (see 5.1.3 c)		N/A
	Cable complies with IEC 60227 or IEC 60245		N/A
	Heat-resistant if likely to contact hot parts	No heat-resistant used	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Temperature rating (cord and inlet)..... :		N/A
	Green/yellow used only for connection to PROTECTIVE CONDUCTOR TERMINALS		N/A
	Detachable cords with IEC 60320 MAINS connectors:		—
	Conform to IEC 60799; or		N/A
	Have the current RATING of the MAINS connector		N/A
6.10.2	Fitting of non-detachable MAINS supply cords		N/A
6.10.2.1	Cord entry		N/A
	a) Inlet or bushing with a smoothly rounded opening; or		N/A
	b) Insulated cord guard protruding >5 D		N/A
6.10.2.2	Cord anchorage		N/A
	Protective earth conductor is the last to take the strain		N/A
	a) Cord is not clamped by direct pressure from a screw		N/A
	b) Knots are not used		N/A
	c) Cannot push the cord into the equipment to cause a HAZARD		N/A
	d) No failure of cord insulation in anchorage with metal parts		N/A
	e) Not to be loosened without a tool		N/A
	f) Cord replacement does not cause a HAZARD and method of strain relief is clear		N/A
	Push-pull and or torque test		N/A
6.10.3	Plugs and connectors		N/A
	MAINS supply plugs, connectors etc., conform with relevant specifications		N/A
	If equipment supplied at voltages below 6.3.2.a) or from a sole source:		—
	Plugs of supply cords do not fit MAINS sockets above rated SUPPLY voltage		N/A
	MAINS type plugs used only for connection to MAINS supply		N/A
	Plug pins which receive a charge from an internal capacitor		N/A
	Accessory MAINS socket outlets:		—
	a) Marking if accepts a standard MAINS supply plug (see 5.1.3e)		N/A
	b) Input has a protective earth conductor if outlet has EARTH TERMINAL CONTACT		N/A
6.11	Disconnection from supply source		N/A
6.11.1	Disconnects all current-carrying conductors		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
6.11.2	Exceptions		N/A
6.11.3	Requirements according to type of equipment		N/A
6.11.3.1	PERMANENTLY CONNECTED EQUIPMENT and multi-phase equipment	Not such type equipment	N/A
	Employs switch or circuit-breaker		N/A
	If switch or circuit-breaker is not part of the equipment, documentation requires:		—
	a) Switch or circuit-breaker to be included in building installation		N/A
	b) Suitable location easily reached		N/A
	c) Marking as disconnecting for the equipment		N/A
6.11.3.2	Single-phase cord-connected equipment		N/A
	Equipment is provided with one of the following:		N/A
	a) Switch or circuit-breaker		N/A
	b) Appliance coupler (disconnectable without tool)		N/A
	c) Separable plug (without locking device)		N/A
6.11.4	Disconnecting devices		N/A
6.11.4.1	Disconnecting device part of equipment		N/A
	Electrically close to the SUPPLY		N/A
	Power-consuming components not electrically located between the supply source and the disconnecting device	No such components used	N/A
	Except electromagnetic interference suppression circuits permitted to be located on the supply side of the disconnecting device		N/A
6.11.4.2	Switches and circuit-breakers	No such components	N/A
	When used as disconnection device:		—
	Meets IEC 60947-1 and IEC 60947-3		N/A
	Marked to indicate function..... :		N/A
	Not incorporated in MAINS cord		N/A
	Does not interrupt PROTECTIVE EARTH CONDUCTOR		N/A
6.11.4.3	Appliance couplers and plugs		N/A
	Where an appliance coupler or separable plug is used as the disconnecting device (see 6.11.3.2):		N/A
	Readily identifiable and easily reached by the operator		N/A
	Single-phase portable equipment cord length not more than 3 m		N/A
	PROTECTIVE EARTH CONDUCTOR connected first and disconnected last		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7	PROTECTION AGAINST MECHANICAL HAZARDS		P
7.1	Equipment does not cause a mechanical HAZARD in NORMAL nor in SINGLE FAULT CONDITION		P
	Conformity is checked by 7.2 to 7.7		P
7.2	Sharp edges	No sharp edges	P
	Easily touched parts are smooth and rounded		P
	Do not cause injury during NORMAL USE and		P
	Do not cause injury during SINGLE FAULT CONDITION		P
7.3	Moving parts	No moving parts.	N/A
7.3.1	HAZARDS from moving parts limited to a tolerable level with the conditions specified in 7.3.2 and 7.3.5		N/A
	Risk assessment in accordance with 7.3.3 carried out		N/A
7.3.2	Exceptions		N/A
	Access to HAZARDOUS moving parts permitted under following circumstances:		N/A
	a) obviously intended to operate on parts or materials external of the equipment		N/A
	inadvertent touching of moving parts minimized by equipment design (e .g. guards or handles)		N/A
	b) If OPERATOR access is unavoidable outside NORMAL USE following precautions have been taken:		N/A
	1) Access requires TOOL		N/A
	2) Statement about training in the instructions		N/A
	3) Warning markings on covers prohibiting access by untrained OPERATORS		N/A
	or symbol 14 with full details in documentation		N/A
7.3.3	RISK assessment for mechanical HAZARDS to body parts		N/A
	Risk is reduced to a tolerable level by protective measures as specified in Table 12		N/A
	Minimum protective measures:		—
	A. Low level measures		N/A
	B. Moderate measures		N/A
	C. Stringent measures		N/A
7.3.4	Limitation of force and pressure		N/A
	Following levels are met in NORMAL and SINGLE FAULT CONDITION:		N/A
	Continuous contact pressure below 50 N / cm ² with force below 150 N		N/A
	Temporary force below 250 N for an area at least of 3 cm ² for a maximum duration of 0,75 s		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.3.5	Gap limitations between moving parts		N/A
7.3.5.1	Access normally allowed		N/A
	If levels of 7.3.4 exceeded and body part may be inserted minimum gap as specified in Table 13 assured in NORMAL and in SINGLE FAULT CONDITION		N/A
7.3.5.2	Access normally prevented		N/A
	Maximum gap as specified in Table 14 assured in NORMAL and in SINGLE FAULT CONDITION		N/A
7.4	Stability		N/A
	Equipment not secured to building structure is physical stable		N/A
	Stability maintained after opening of drawers etc. by automatic means, or		N/A
	warning marking requires the application of means		N/A
	Compliance checked by following tests as applicable:		—
	a) 10° tilt test for other than handheld equipment		N/A
	b) multi-directional force test for equipment exceeds height of 1 m and mass of 25 kg		N/A
	c) downward force test for floor-standing equipment	Not floor-standing equipment	N/A
	d) overload test with 4 times maximum load for castor or support that supports greatest load		N/A
	e) castor or support that supports greatest load removed from equipment		N/A
7.5	Provisions for lifting and carrying		N/A
7.5.1	Equipment more than 18 kg :		—
	Has means for lifting or carrying; or		N/A
	Directions in documentation		N/A
7.5.2	Handles and grips		N/A
	Handles or grips withstand four times weight		N/A
7.5.3	Lifting devices and supporting parts		N/A
	RATED for maximum load; or		N/A
	tested with four times maximum static load		N/A
7.6	Wall mounting		N/A
	Mounting brackets withstand four times weight		N/A
7.7	Expelled parts	No such expelled parts	N/A
	Equipment contains or limits the energy		N/A
	Protection not removable without the aid of a tool		N/A
8	RESISTANCE TO MECHANICAL STRESSES		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.1	Equipment does not cause a HAZARD when subjected to mechanical stresses in NORMAL USE		N/A
	Normal protection level is 5 J		N/A
	Levels below 5 J but not less than 1 J are acceptable if all of following criteria are met:		N/A
	a) lower level justified by RISK assessment of manufacturer		N/A
	b) equipment installed in its intended application is not easily touched		N/A
	c) only occasional access during NORMAL USE		N/A
	d) IK code in accordance to IEC 62262 marked or symbol 14 used with full information in the documentation		N/A
	For non-metallic ENCLOSURES rated below 2 °C ambient temperature value chosen for minimum RATED temperature		N/A
	Impact energies between IK values, the IK code marked for nearest lower value		N/A
	Conformity is checked by performing following tests:		—
	1) static test of 8.2.1		N/A
	2) impact test of 8.2.2 with 5 J except for HAND-HELD EQUIPMENT		N/A
	if impact energy not selected to 5 J alternate method of IEC 62262 used		N/A
	3) drop test of 8.3.1 or 8.3.2 except for FIXED EQUIPMENT with mass over 100 kg		N/A
	Equipment RATED with an impact rating of IK 08 that obviously meets the criteria		N/A
	After the tests inspection with following results:		—
	- HAZARDOUS LIVE parts above the limits of 6.3.2 not ACCESSIBLE		N/A
	- insulation pass the voltage tests of 6.8	(see Form A.30)	N/A
	i) no leaks of corrosive and harmful substances		N/A
	ii) ENCLOSURE shows no cracks resulting in a HAZARD		N/A
	iii) CLEARANCES not less than their permitted values		N/A
	iv) insulation of internal wiring remains undamaged		N/A
	v) PROTECTIVE BARRIERS not damaged or loosened		N/A
	vi) No moving parts exposed, except permitted by 7.3		N/A
	vii) no damage which could cause spread of fire		N/A
8.2	ENCLOSURE rigidity test		N/A
8.2.1	Static test	(see Form A.21)	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	- 30 N with 12 mm rod to each part of ENCLOSURE		N/A
	- in case of doubt test conducted at maximum RATED ambient temperature		N/A
8.2.2	Impact test	(see Form A.21)	N/A
	Impact applied to any part of ENCLOSURE causing a HAZARD if damaged		N/A
	Impact energy level and corresponding IK code :		N/A
	Non-metallic ENCLOSURES cooled to minimum RATED ambient temperature if below 2 °C		N/A
8.3	Drop test	(see Form A.21)	N/A
8.3.1	Other than HAND-HELD and DIRECT-PLUG-IN EQUIPMENT		N/A
	Tests conducted with a drop height or angle of :		N/A
8.3.2	HAND-HELD and DIRECT-PLUG-IN EQUIPMENT	Not such type equipment	N/A
	Non-metallic ENCLOSURES cooled to minimum RATED ambient temperature if below 2 °C		N/A
	Drop test conducted with an height of 1 m		N/A

9	PROTECTION AGAINST THE SPREAD OF FIRE		P
9.1	No spread of fire in NORMAL and SINGLE FAULT CONDITION		P
	MAINS supplied equipment meets requirements of 9.6 additionally		N/A
	Conformity is checked by minimum one or a combination of the following (see Figure 11):	(see Form A.22)	P
	a) SINGLE FAULT test of 4.4; or	(see Forms A.1)	P
	b) Application of 9.2 (eliminating or reducing the sources of ignition); or		P
	c) Application of 9.3 (containment of fire within the equipment)		P
9.2	Eliminating or reducing the sources of ignition within the equipment		P
	a) 1) Limited-energy circuit (see 9.4); or	The battery comply the limits of table 13, also see 9.4	P
	2) BASIC INSULATION provided for parts of different potential; or		N/A
	Bridging the insulation does not cause ignition		N/A
	b) Surface temperature of liquids and parts (see 9.5)		N/A
	c) No ignition in circuits designed to produce heat		N/A
9.3	Containment of the fire within the equipment, should it occur		P

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Clause	Requirement + Test	Result - Remark	Verdict
9.3.1	Spread of fire outside equipment reduced to a tolerable level if:		P
	a) Energizing of the equipment is controlled by an OPERATOR held switch	No such switch	N/A
	b) ENCLOSURE is conform with constructional requirements of 9.3.1; and		P
	Requirements of 9.5 are met		N/A
9.3.2	Constructional requirements		P
	a) Connectors and insulating material have flammability classification V-2 or better	(see Table: 1 or Form A.23)	P
	b) Insulated wires and cables are flame retardant (VW-1 or equivalent)	(see Table: 1 or Form A.23)	P
	c) ENCLOSURE meets following requirements:	(see Form A.22)	P
	1) Bottom and sides in arc of 5 ° (see Figure 13) to non-limited circuits (9.4) meets:		P
	i) no openings; or		P
	ii) perforated as specified in Table 16; or		N/A
	iii) metal screen with a mesh; or		N/A
	iv) baffles as specified in Figure 12		N/A
	2) Material of ENCLOSURE and any baffle or flame barrier is made of:		P
	Metal (except magnesium); or		N/A
	Non-metallic materials have flammability classification V-1 or better	(see Table: 1 or Form A.22)	P
	3) ENCLOSURE and any baffle or flame barrier have adequate rigidity		N/A
9.4	Limited-energy circuit		P
	a) Potential not more than 30 r.m.s. and 42,4 V peak, or 60 V dc	(see Form A.18) for battery evaluation.	P
	b) Current limited by one of following means:		P
	1) Inherently or by impedance (see Table 17); or	Battery comply limits of table 13 under normal and fault condition	P
	2) Overcurrent protective device (see Table 18); or		N/A
	3) A regulating network limits also in SINGLE FAULT CONDITION (see Table 17)		N/A
	c) Is separated by at least BASIC INSULATION		N/A
	Fuse or a nonadjustable electromechanical device is used		N/A
9.5	Requirements for equipment containing or using flammable liquids	No flammable liquids used	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Flammable liquids contained in or specified for use with equipment do not cause spread of fire		N/A
	RISK is reduced to a tolerable level :		N/A
	a) The temperature of surface or parts in contact with flammable liquids is 25 °C below fire point		N/A
	b) The quantity of liquid is limited		N/A
	c) Flames are contained within the equipment		N/A
	Detailed instructions for RISK-reduction provided		N/A
9.6	Overcurrent protection		N/A
9.6.1	MAINS supplied equipment protected		N/A
	BASIC INSULATION between MAINS parts of opposite polarity provided		N/A
	Devices not in the protective conductor		N/A
	Fuses or single-pole circuit-breakers not fitted in neutral (multi-phase)		N/A
9.6.2	PERMANENTLY CONNECTED EQUIPMENT	Not permanently connected equipment	N/A
	Overcurrent protection device:		N/A
	Fitted within the equipment; or		N/A
	Specified in manufacturer's instructions		N/A
9.6.3	Other equipment		N/A
	Protection within the equipment		N/A

10	EQUIPMENT TEMPERATURE LIMITS AND RESISTANCE TO HEAT		P
10.1	Surface temperature limits for protection against burns		P
	Easily touched surfaces within the limits in NORMAL and in SINGLE FAULT CONDITION:	(see Form A.26A)	P
	- at an specified ambient temperature of 40 °C		P
	- for equipment rated above 40 °C ambient temperature limits not exceeded raised by the difference to 40 °C	Rated 40°C	N/A
	Heated surfaces necessary for functional reasons exceeding specified values:		N/A
	Are recognizable as such by appearance or function; or		N/A
	Are marked with symbol 13		N/A
	Guards are not removable without tool		N/A
10.2	Temperatures of windings		N/A
	Limits not exceeded in:		N/A
	NORMAL CONDITION		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	SINGLE FAULT CONDITION		N/A
10.3	Other temperature measurements		P
	Following measurements conducted if applicable:	(see Form A.26A)	P
	a) Value of 60 °C of field-wiring terminal box not exceeded		N/A
	b) Surface of flammable liquids and parts in contact with this liquids		N/A
	c) Surface of non-metallic ENCLOSURES		P
	d) Parts made of insulating material supporting parts connected to MAINS supply		N/A
	e) Terminals carrying a current more than 0,5 A		N/A
10.4	Conduct of temperature tests		P
10.4.1	Tests conducted under reference test conditions and manufacturer's instructions	(see Form A.26A)	P
10.4.2	Temperature measurement of heating equipment		N/A
	Tests conducted in test corner		N/A
10.4.3	Equipment intended for installation in a cabinet or wall		N/A
	Equipment built in as specified in installation instructions		N/A
10.5	Resistance to heat		N/A
10.5.1	Integrity of CLEARANCE and CREEPAGE DISTANCES		N/A
10.5.2	Non-metallic ENCLOSURES		N/A
	Within 10 min after treatment:		—
	Equipment subjected to suitable stresses of 8.2 and 8.3 complying with criteria of 8.1		N/A
10.5.3	Insulating material		N/A
	a) Parts supporting parts connected to MAINS supply		N/A
	b) TERMINALS carrying a current more than 0,5 A		N/A
	Examination of material data; or		N/A
	in case of doubt:		N/A
	1) Ball pressure test; or		N/A
	2) Vicat softening test of ISO 306		N/A

11	PROTECTION AGAINST HAZARDS FROM FLUIDS		P
11.1	Protection to OPERATORS and surrounding area provided by EQUIPMENT		P
	All fluids specified by manufacturer considered		P
11.2	Cleaning		P
11.3	Spillage		P

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Clause	Requirement + Test	Result - Remark	Verdict

11.4	Overflow		P
11.5	Battery electrolyte		P
	Battery electrolyte leakage presents no HAZARD		P
11.6	Specially protected equipment		N/A
11.7	Fluid pressure and leakage		N/A
11.7.1	Maximum pressure :		N/A
	Maximum pressure of any part does not exceed P_{RATED}		N/A
11.7.2	Leakage and rupture at high pressure		N/A
	Fluid-containing parts subjected to hydraulic test if:		N/A
	a) product of pressure and volume > 200 kPa; and		N/A
	b) pressure > 50 kPa		N/A
	Parts of refrigerating systems meets pressure-related requirements of IEC 60335-24 or IEC 60335-2-89		N/A
11.7.3	Leakage from low-pressure parts		N/A
11.7.4	Overpressure safety device		N/A
	Does not operate in NORMAL USE		N/A
	a) Connected as close as possible to parts intended to be protected		N/A
	b) Easy access for inspection, maintenance and repair		N/A
	c) Adjustment only with TOOL		N/A
	d) No discharge towards person		N/A
	e) No HAZARD from deposit of discharged material		N/A
	f) Adequate discharge capacity		N/A
	No shut-off valve between overpressure safety device and protected parts		N/A

12	PROTECTION AGAINST RADIATION, INCLUDING LASER SOURCES, AND AGAINST SONIC AND ULTRASONIC PRESSURE		P
12.1	Equipment provides protection		N/A
12.2	Equipment producing ionizing radiation		N/A
12.2.1	Ionizing radiation		N/A
12.2.1.1	Equipment meets the following requirements:		N/A
	a) if intended to emit radiation meets requirements of 12.2.1.2; or		N/A
	tested, classified and marked in accordance to IEC 60405		N/A
	b) if only emits stray radiation meets requirements of 12.2.1.3		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
12.2.1.2	Equipment intended to emit radiation		N/A
	Effective dose rate of radiation measured..... :		N/A
	If dose rate exceeds 5 µSv/h marked with the following:		N/A
	a) Symbol 17 (ISO 361)		N/A
	b) Abbreviations of the radionuclides :		N/A
	c) With maximum dose at 1 m; or :		N/A
	with dose rate value between 1 µSv/h and 5 µSv/h in m..... :		N/A
12.2.1.3	Equipment not intended to emit radiation		N/A
	Limit for unintended stray radiation of 1 µSv/h at any easily reached point kept :		N/A
12.2.2	Accelerated electrons		N/A
	Compartments opened only by the use of a TOOL		N/A
12.3	Ultraviolet (UV) radiation		N/A
	No unintentional HAZARDOUS escape of UV radiation:		—
	- checked by inspection; and		N/A
	- evaluation of RISK assessment documentation		N/A
12.4	Microwave radiation		N/A
	Power density does not exceed 10 W/m ² :		N/A
12.5	Sonic and ultrasonic pressure		N/A
12.5.1	Sound level		N/A
	No HAZARDOUS sound emission		N/A
	Maximum sound pressure level measured and calculated for maximum sound power level as specified in ISO 3746 or ISO 9614-1		N/A
	Instruction describes measures for protection		N/A
12.5.2	Ultrasonic pressure		N/A
	Equipment not intended to emit ultrasound does not exceed limit of 110 dB between 20 kHz and 100 kHz		N/A
	Equipment intended to emit ultrasound:		N/A
	Outside useful beam does not exceed limit of 110 dB between 20 kHz and 100 kHz		N/A
	If inside useful beam above values exceeded:		N/A
	Marked with Symbol 14 of Table 1		N/A
	and following information in the documentation:		N/A
	a) dimensions of useful beam		N/A
	b) area where ultrasonic pressure exceed 110 dB		N/A
	c) maximum sound pressure inside beam area		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

12.6	Laser sources		N/A
	Equipment meets requirements of IEC 60825-1		N/A

13	PROTECTION AGAINST LIBERATED GASES AND SUBSTANCES, EXPLOSION AND IMPLOSION		P
13.1	Poisonous and injurious gases and substances		N/A
	No poisonous or injurious gases or substances liberated in NORMAL CONDITION		N/A
	Attached data/test reports demonstrate conformity		N/A
13.2	Explosion and implosion		N/A
13.2.1	Components		N/A
	Components liable to explode:		—
	Pressure release device provided; or		N/A
	Apparatus incorporates operator protection (see also 7.7)		N/A
	Pressure release device:		—
	Discharge without danger		N/A
	Cannot be obstructed		N/A
13.2.2	Batteries and battery charging	Rechargeable Li-ion used also see Form A.27.	P
	If explosion or fire HAZARD could occur:		—
	Protection incorporated in the equipment; or	Short-circuit performed between “+” and “-“ of the battery, no fire or leakage observed. See Form A.27	P
	Instructions specify batteries with built-in protection		N/A
	In case of wrong type of battery used:		—
	No HAZARD; or	Other type of battery with different property cannot be properly installed in the battery compartment.	P
	Warning by marking and within instructions	Warning information specified in user manual and on battery pack.	P
	Equipment with means to charge rechargeable batteries:	See above.	—
	Warning against the charging of non-rechargeable batteries; and	See above	N/A
	Type of rechargeable battery indicated; or		N/A
	Symbol 14 used		N/A
	Battery compartment design		P
	Single component failure	See Form A.27	P

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Clause	Requirement + Test	Result - Remark	Verdict

	Polarity reversal test	See above.	P
13.2.3	Implosion of cathode ray tubes		N/A
	If maximum face dimensions > 160 mm :		—
	Intrinsically protected and correctly mounted; or		N/A
	ENCLOSURE provides protection:		N/A
	If non-intrinsically protected:		—
	Screen not removable without TOOL		N/A
	If glass screen, not in contact with surface of tube		N/A

14	COMPONENTS AND SUBASSEMBLIES		P
14.1	Where safety is involved, components and subassemblies meet relevant requirements	(see Table 1)	P
14.2	Motors		N/A
14.2.1	Motor temperatures		N/A
	Does not present a HAZARD when stopped or prevented from starting; or	(see Form A.1)	N/A
	Protected by over-temperature or thermal protection device conform with 14.3		N/A
14.2.2	Series excitation motors	No such motors	N/A
	Connected direct to device, if overspeeding causes a HAZARD		N/A
14.3	Overtemperature protection devices		N/A
	Devices operating in a SINGLE FAULT CONDITION		N/A
	a) Reliable function is ensured		N/A
	b) RATED to interrupt maximum current and voltage		N/A
	c) Does not operate in NORMAL USE		N/A
	If self-resetting device used to prevent a HAZARD, protected part requires intervention before restarting		N/A
14.4	Fuse holders		N/A
	No access to HAZARDOUS LIVE parts		N/A
14.5	MAINS voltage selecting devices		N/A
	Accidental change not possible		N/A
14.6	MAINS transformers tested outside equipment		N/A
14.7	Printed circuit boards		P
	Data shows conformity with V-1 of IEC 60695-11-10 or better; or	UL approved with V-0	P
	Test shows conformity with V-1 of IEC 60695-11-10 or better		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Not applicable for printed wiring boards with limited-energy circuits (9.4)		N/A
14.8	Circuits or components used as TRANSIENT OVERVOLTAGE limiting devices		N/A
	Test conducted between each pair of MAINS SUPPLY TERMINALS		N/A
	No HAZARD resulting from rupture or overheating of the component:		N/A
	- no bridging of safety relevant insulation		N/A
	- no heat to other parts above the self-ignition points		N/A
15	PROTECTION BY INTERLOCKS		N/A
15.1	Interlocks are designed to remove a HAZARD before OPERATOR exposed		N/A
15.2	Prevention of reactivation		N/A
15.3	Reliability		N/A
	Single fault unlikely to occur; or		N/A
	Cannot cause a HAZARD		N/A
16	HAZARDS RESULTING FROM APPLICATION		N/A
16.1	REASONABLY FORESEEABLE MISUSE		N/A
	No HAZARDS arising from settings not intended and not described in the instructions		N/A
	Other cases of REASONABLY FORESEEABLE MISUSE addressed by RISK assessment		N/A
16.2	Ergonomic aspects		N/A
	Factors giving rise to a HAZARD the RISK assessment is reflecting those aspects:		N/A
	a) limitation of body dimensions		N/A
	b) displays and indicators		N/A
	c) accessibility and conventions of controls		N/A
	d) arrangement of TERMINALS		N/A
17	RISK ASSESSMENT		N/A
	RISK assessment conducted, if HAZARD might arise and not covered by Clauses 6 to 16		N/A
	TOLERABLE RISK achieved by iterative documented process covering the following:		N/A
	a) RISK analysis		N/A
	Identifies HAZARDS and estimates RISK		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) RISK evaluation		N/A
	Plan to judge acceptability of resulting RISK level based on the estimated severity and likelihood of a RISK		N/A
	c) RISK reduction		N/A
	Initial RISK reduced by counter measures;		N/A
	Repeated RISK evaluation without new RISKS introduced		N/A
	RISKS remaining after RISK assessment addressed in instructions to RESPONSIBLE BODY:		N/A
	Information contained how to mitigate these RISKS		N/A
	Following principles in methods of RISK reduction applied by manufacturer in given order:		N/A
	1) RISKS eliminated or reduced as far as possible		N/A
	2) Protective measures taken for RISKS that cannot be eliminated		N/A
	3) User information about residual RISK due to any defect of the protective measures		N/A
	Indication of particular training is required		N/A
	Specification of the need for personal protective equipment		N/A
	Conformity checked by evaluation of the RISK assessment documentation		N/A
ANNEX F	ROUTINE TESTS		N/A
	Manufacturer 's declaration		N/A

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Clause	Requirement — Test	Result — Remark	Verdict

4.4	TABLE: Testing in SINGLE FAULT CONDITION – Results			Form A.1.	P
Test subclause	Fault No.	Fault description	Td 4.4.3 (NOTE)	How was test terminated Comments	Meets 4.4.4
Discharging-Operate charged battery (8.4V, 1.8A) (Display with highest brightness, testing the drug continuously)					
4.4.2.7	1	R74 s-c	10minutes	Unit normally working. Battery discharge current is 0.81A. No hazards. No leakage. No fire.	P
4.4.2.7	2	U18 pin 3-4 s-c	10minutes	Unit normally working. Battery discharge current is 0.81A. No hazards. No leakage. No fire.	P
4.4.2.7	3	U24 pin 2-3 s-c	10minutes	Unit shutdown immediately, Battery discharge current reduce from 0.81A → 0A. Recoverable, no hazards. No leakage. No fire.	P
4.4.2.7	4	C73 (Battery) s-c	10minutes	Unit shutdown immediately, Battery discharge current reduce from 0.81A → 0A. Recoverable, no hazards. No leakage. No fire.	P
4.4.2.7	5	Stepper DC motor lock	10minutes	Unit stops printing, and discharge current is 0.81A. Recoverable, no hazards. No leakage. No fire.	P
Charging-Operate via output of external adaptor (9V, 2.5A)					
4.4.2.7	1	D7 s-c	10minutes	Unit normally working. Battery charge current is 0.98A No hazards. No leakage. No fire.	P
4.4.2.7	2	U19 pin 12-15 s-c	10minutes	Unit shutdown immediately, Battery charge current reduce from 0.81A → 0A. Recoverable, no hazards. No leakage. No fire.	P
4.4.2.7	3	C73 s-c	10minutes	Unit shutdown immediately, Battery charge current reduce from 0.81A → 0A. Recoverable, no hazards. No leakage. No fire.	P
4.4.2.7	4	R74 pin 1-8 s-c	10minutes	Unit normally working. Battery charge current is 0.98A No hazards. No leakage. No fire.	P
NOTE Td = Test duration in hh:mm:ss Record dielectric strength test on Form A.19 and temperature tests on Form A.27A and or A.27.B. Record in the comments column for each test whether carried out during or after SINGLE FAULT CONDITION.					
Supplementary information: s-c = short circuit					

TESTED BY: _____ DATE: _____ TEST EQUIPMENT LIST ITEM _____

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Clause	Requirement — Test	Result — Remark	Verdict		
5.3	TABLE: Durability of markings	Form A.3	P		
Marking method (see NOTE)		Agent			
1) Label material		A Water			
2) fixing (molded)		B Isopropyl alcohol 70%			
3) print		C (specify agent)			
		D (specify agent)			
		E (specify agent)			
NOTE – Where applicable include print method, label material, ink or paint type, fixing method, adhesive and surface to which marking is fixed.					
Marking location			Marking method (see above)		
Identification (5.1.2)			3, 2		
MAINS supply (5.1.3)			N/A		
Fuses (5.1.4)			N/A		
Terminals and operating devices (5.1.5.2)			N/A		
Switches and circuit breakers (5.1.6)			N/A		
Double/reinforced equipment (5.1.7)			N/A		
Field wiring Terminal boxes (5.1.8)			N/A		
Warning marking (5.2)			N/A		
Battery charging (13.2.2)			N/A		
Method	Test agent	Remains legible	Label loose	Curled edges	Comments
		Verdict	Verdict	Verdict	
See above 2	B	Pass	Pass	Pass	N/A
See above 3	B	Pass	Pass	Pass	N/A
Supplementary information:					

TESTED BY: _____ DATE: _____ TEST EQUIPMENT LIST ITEM: _____

IEC 61010-1			
Clause	Requirement — Test	Result — Remark	Verdict

9	TABLE: Protection against the spread of fire			Form A.22	P
Item	Source of HAZARD or area of the equipment considered (circuit, component, liquid etc.)	Protection Method (9a, 9b or 9c)	Protection details	Verdict	
1	Battery	9b	Battery fault conditions performed, see Form A.24	P	
2	Main board	9c	Enclosure rated V-0, PCB rated V-0	P	

Supplementary information:

TESTED BY: _____ DATE: _____ TEST EQUIPMENT LIST ITEM _____

Clause	Requirement — Test	Result — Remark	Verdict
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9.4	TABLE: Limited-energy circuit					Form A.24	P
Item	9.4 a)	9.4 b) Current limitation (NOTE)		9.4 c)	Decision		
or Location (see Form A.17)	Maximum potential in circuit voltage r.m.s./d.c. V	Maximum available current A	Overload protection after 120 s A	Circuit separation	Yes/No	Comments	
Battery s-c	8.4	--	4.77	--	Yes	Current increases to 4.77A for 5min then EUT not operate. No hazards. Limit: 100/U=11.9A	
NOTE – Maximum values see Tables 17 and 18.of 61010-1							
Supplementary information:							

TESTED BY: _____ DATE: _____ TEST EQUIPMENT LIST ITEM _____

IEC 61010-1			
Clause	Requirement — Test	Result — Remark	Verdict

10.	TABLE : Temperature Measurements			Form A.26A	P
10.1	Surface temperature limits - NORMAL CONDITION				P
10.2	Temperature of windings- NORMAL CONDITION				N/A
10.3	Other temperature measurements				P
Operating conditions:		Operate while linking Bluetooth connection			
Frequency		-- Hz	Test room ambient temperature (t_a) ..:		20.8 °C
Voltage		See below V	Test duration		0 h 41 min.
Part / Location		t_m °C	t_c °C	t_{max} °C	Verdict
Comments					
Discharging-Operate charged battery (8.4V, 1.8A) (Display with highest brightness, testing the drug continuously)					
Enclosure (outside near DC motor)	33.1	51.6	85	P	Limit of non-metallic enclosure
Side Button (outside)	27.8	46.3	85	P	Limit of non-metallic enclosure
Battery cover (outside)	29.1	47.6	85	P	Limit of non-metallic enclosure
LCD panel	30.2	48.7	80	P	Limit of glass panel
Battery	31.5	50.0	--	P	Reference
Main board PCB near U12	36.7	55.2	130	P	Component limit
Measurement board	34.9	53.4	130	P	Component limit
Bluetooth board	43.9	62.4	130	P	Component limit
LED module	35.9	54.4	130	P	Component limit
Internal wire	32.9	51.4	85	P	Component limit
Printing board	40.4	58.9	130	P	Component limit
DC stepper motor	56.7	75.2	100	P	Component limit
Ambient:	21.5	40	--	--	--
Charging-Operate via output of external adaptor (9V, 2.5A)					
Enclosure of adaptor (external)	31.3	50.5	85	P	Limit of non-metallic enclosure
Enclosure (outside near DC motor)	33.8	53.0	85	P	Limit of non-metallic enclosure
Side Button (outside)	28.2	47.4	85	P	Limit of non-metallic enclosure
Battery cover (outside)	34.0	53.2	85	P	Limit of non-metallic enclosure
LCD panel	32.5	51.7	80	P	Limit of glass panel
Battery	30.1	49.3	--	P	Reference

IEC 61010-1			
Clause	Requirement — Test	Result — Remark	Verdict

10.	TABLE : Temperature Measurements	Form A.26A	P
10.1	Surface temperature limits - NORMAL CONDITION		P
10.2	Temperature of windings- NORMAL CONDITION		N/A
10.3	Other temperature measurements		P

Operating conditions:	Operate while linking Bluetooth connection		
Frequency	-- Hz	Test room ambient temperature (t_a) ..:	20.8 °C
Voltage	See below V	Test duration	0 h 41 min.

Part / Location	t_m °C	t_c °C	t_{max} °C	Verdict	Comments
Main board PCB near U12	41.6	60.8	130	P	Component limit
Measurement board	37.9	57.1	130	P	Component limit
Bluetooth board	44.7	63.9	130	P	Component limit
LED module	37.3	56.5	130	P	Component limit
Internal wire	34.0	53.2	85	P	Component limit
Printing board	41.0	60.2	130	P	Component limit
DC stepper motor	56.3	75.5	100	P	Component limit
Ambient:	20.8	40	--	--	--

NOTE 1 - t_m = measured temperature

t_c = t_m corrected ($t_m - t_a + 40$ °C or max. RATED ambient)

t_{max} = maximum permitted temperature

NOTE 2 - see also 14.1 with reference to component operating conditions

NOTE 3 - Record values for NORMAL CONDITION and / or SINGLE FAULT CONDITION in this Form use additional form if necessary

NOTE 4 - see Form A.26B for details of winding temperature measurements

Supplementary information: Max. ambient temperature is evaluated up to 40°C

TESTED BY: _____ DATE: _____ TEST EQUIPMENT LIST ITEM: _____

IEC 61010-1			
Clause	Requirement — Test	Result — Remark	Verdict

13.2.2	TABLE: Batteries	Form A.37.	P
	Battery load and charging circuit diagram:		
	Battery type.....:	Rechargeable Li-ion battery	—
	Battery manufacturer/model/catalogue No.....:	See table 1	—
	Battery ratings	See table 1	—
	Reverse polarity instalment test	No leakage, fire or explosion	P
Single component failures		Verdict	
Component		Open circuit	Short circuit
Battery s-c		--	See Form A.1
Supplementary information: The battery separate evaluated with standard of EN 62133.			

TESTED BY: _____ DATE: _____ TEST EQUIPMENT LIST ITEM: _____

IEC 61010-1			
Clause	Requirement — Test	Result — Remark	Verdict

TABLE: 1 - List of components and circuits relied on for safety						P
Unique component reference or location	Application/function	Manufacturer / trademark (NOTE 1)	Type / model	Technical data (NOTE 2)	Standard	Mark(s) of conformity evidence of acceptance (NOTE 3 and 4)
Adaptor	Power	Shenzhen Huntkey Electric CO LTD	HKA02409025-7R	Input: 100-240Vac, 50/60Hz, 1.0A Output: 7.0-9.0 Vdc, 1.5-2.5A, LPS, 40°C	IEC 60950-1:2005 (Second Edition); Am1:2009 + Am2:2013	UL CB DK-40543-UL
Enclosure	Mechanical protection	LG Chemical Ltd	AF312	V-0, 85°C Min. thickness:1.5mm	UL 94	UL E67171
Battery	Power	High capacity lithium battery	723759	7.4V, 1800mAh, 13.32Wh	--	TUV Rheinland report 17055129 001
PCB	Electrical component	Interchangeable	Interchangeable	V-0, 130°C	UL 796	UL
Printing module	Electrical component	Xiamen PURUITE	HSI-48-A	3.5V~ 9.5V, 2.6A, 85mm/s, 50°C	EN 61010-1	Tested with compliance
LED Module (OEM Scan Engine)	Electrical component	Fujian Newland Auto-ID Tech Co., Ltd.	NLS-EM3096	DC 3.3V, 230mA, Exempt group	IEC/EMN62471	Test report by EMTEK ED150811131S
NOTE → 1 List all different manufacturers of the above components → 2 May include electrical, mechanical values → 3 List licence no or method of acceptance → 4 asterisk indicates mark assuring agreed level of surveillance						

	Eq. No.	Name	Manufacturer	Model No.	Date of Calibration	Date of next Calibration
X	1.116	Dual Display Multimeter	Fluke	F45	2015.04.20	2016.04.19
X	1.120	Data Acquisition Switch Unit	Agilent Technologies	34970A	2015.05.13	2016.05.12
X	1.127	Digital Power Meter	YOKOGAWA	WT210	2015.05.25	2016.05.24
X	1.150	Table Top Multimeter	Agilent Technologies	34405A	2015.09.09	2016.09.08
X	1.245	Timer	TIANFU	PC396	2014.07.22	2016.07.21
X	3.315	Test Wire D=1,0mm (EN 60529)	Guangdong Test Technic Development Co.		2005.03.29	*)

*) Initial calibration or verification only

Statement of Uncertainty


Unless otherwise specified, combined measurement uncertainty for values stated in the test report is as stated below:

Voltage measurement:	±1.50% (true rms value)
	±1.20% (DC voltage)
Current measurement:	±1.56% (true rms value)
	±1.40% (DC current)
Power	- less than 1 W
	±20 mW
	- below 3 kW
	±0.53%
	- 3 kW and more
	±0.58%
Power factor	±0.01
Frequency	±0.06%
Resistance	- between 100 mΩ and 1 MΩ
	±1.25%
	- another values
	±2.05%
Temperature	- below 100°C
	±1.25°C (without thermocouple; for thermocouple add 2°C)
	- between 100 and 500°C
	±1.45°C (without thermocouple; for thermocouple add 2°C)
Time	- below 20 s
	±0.74%
	- more than 20 s (manual meas.)
	±0.2 s
Linear dimensions	- less than 1 mm
	- from 1 to 25 mm
	±0.05 mm
	- more than 25 mm
	±0.30%
Mass	- below 5 kg
	±2%
	- 5 kg and more
	±1%
Force	±1%
Relative humidity	±5%
Air pressure (barometric)	±0.2 kPa
Pressure	±3.34%
Flow	±1.5%

Values stated in this document represent the worst case for equipment which is in possession of the laboratory and setups commonly used for testing.

For units or cases not specified in this document the evaluation of uncertainty shall be made upon request on individual basis.

The reported combined uncertainty is stated as standard uncertainty of reported value multiplied by coverage factor $k = 2$, which for normal distribution corresponds to a coverage probability of approximately 95%.

TEST REPORT IEC 61010-2-101 / EN 61010-2-101 Safety requirements for electrical equipment for measurement, control, and laboratory use Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	
Report Reference No.	17050498 001
Compiled by (+ signature)	See cover page
Approved by (+ signature)	See cover page
Date of issue.....	See cover page
CB / CCA Testing Laboratory	See cover page
Address	See cover page
Testing location	See cover page
Address	See cover page
Applicant's name	See cover page
Address	See cover page
Test specification:	
Standard	See cover page
Test procedure	See cover page
Non-standard test method	N/A
Test Report Form No.	IECEN61010_2_101A
TRF Originator	VDE
Master TRF	Dated February 2004
Copyright © 2004 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved. This publication may be reproduced in whole or in part for non-commercial purposes as long as the IECEE is acknowledged as copyright owner and source of the material. IECEE takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context.	
Test item description	Drug Test Analyzer
Trade Mark	 AquilaScan
Manufacturer	Same as applicant
Model/Type reference	WDTP-10
Ratings	DC9V,2.5A (via external approved adaptor) DC 7.4V (via Lithium-Ion rechargeable battery)


Copy of marking plate:

See EN 61010-1 test report

Summary of testing:

See EN 61010-1 test report

Test item particulars	
Type of item tested	Measurement /Control/ Laboratory
Description of equipment function	See EN 61010-1 test report
Installation/overvoltage category	N/A
Pollution degree	N/A
Environmental rating	standard /extended (specify):
Equipment mobility	portable / hand-held / floorstanding / fixed / built in
Connection to mains supply	Permanent/detachable cord set/non detachable cord set / none
Operating conditions	Continuous /short time/ intermittent
Overall size of the equipment (W x D x H)	See EN 61010-1 test report
Mass of the equipment (kg)	See EN 61010-1 test report
Marked degree of protection to IEC 60529	See EN 61010-1 test report
Accessories and detachable parts included	Drug Test Cassette
Other options included	None
Possible test case verdicts:	
- test case does not apply to the test object	
- test object does meet the requirement	
- test object does not meet the requirement	
General remarks:	
<p>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.</p> <p>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 testing laboratory. "(see Enclosure #)" refers to additional information appended to the report. "(see appended table)" refers to a table appended to the report. Throughout this report, a point (coma) is used as the decimal separator.</p> <p>List of test equipment must be kept on file and available for review.</p> <p>This Test Report is intended for the investigations of laboratory equipment for in vitro diagnostic (IVD) use and shall not be used without the CB Test Report covering the evaluation of the product according to IEC 61010-1, Part 1, General Requirements.</p> <p>This Test Report includes the assessment of group differences to complete the assessment according to the last valid edition the relevant EN standards. Those requirements / differences are included at the end of the test case section (main body).</p>	
General product information:	
See EN 61010-1 test report.	

IEC 61010-2-101 / EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
5.	MARKING AND DOCUMENTATION		P
5.1.1	General		P
	Additional symbols cannot be confused with the international ones		P
5.1.2	Identification		P
	Equipment is identified by:		P
5.1.2a)	Manufacturer's name or trademark and address		P
5.1.2b)	Model number, name or other means	WDTP-10	P
5.1.2c)	The name and address of the authorized representative of the manufacturer	In user manual.	P
	The equipment or packaging or the instructions for use include:		N/A
	1) The serial-number or the batch code preceded by "LOT" symbol 102 of table 1		N/A
	2 i) Indication that the equipment is IVD medical equipment		N/A
	2 ii) Indication that the equipment is self-test IVD medical equipment		N/A
	2 iii) Identification of detachable components		N/A
	2 iv) Expiry date of consumable parts		N/A
5.1.101	Transport and storage		N/A
	Packaging labelled to indicate special conditions for transport or storage		N/A
5.2	Warning markings		P
	Potentially infectious equipment marked with symbol 101 of table 1	Marked in user manual and on product near cassette insertion slot.	P
	Equipment that can be hazardous due to the use of chemical substances marked with the appropriate symbol; or		N/A
	with Symbol 14 of Table 1 (if none is available)		N/A
	Containers or bags for biohazardous waste material which can be removed from the equipment during NORMAL USE marked with symbol 101 of table 1	See above.	P
5.3	Durability of markings		P
	The required markings resist the effects of temperature and rubbing, and of solvent and reagents likely to be encountered in NORMAL USE	See EN 61010-1 test report.	P
	Resistant also against agents specified by manufacturer for cleaning and decontamination procedure	See EN 61010-1 test report.	P

IEC 61010-2-101 / EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
5.4	Documentation		P
5.4.1	General		N/A
	Information about any RISKS not reduced to a TOLERABLE RISK level		N/A
	Information included in documentation on:		N/A
	Training; or		N/A
	Protective devices; or		N/A
	Personal protective equipment to reduce RISKS to a TOLERABLE RISK level specified:		N/A
5.4.3	Equipment transportation, installation and assembly instructions		P
	Documentation for the RESPONSIBLE BODY includes:		P
5.4.3.a)	Instructions for transportation after delivery to the RESPONSIBLE BODY		N/A
5.4.3.b)	Floor loading requirements		N/A
5.4.3.c)	Individual weights of principal heavy subassemblies		N/A
5.4.3.d)	Location and mounting instructions		N/A
5.4.3.e)	Assembly instructions		N/A
5.4.3.f)	Instructions for protective earthing		N/A
5.4.3.g)	The sound data required by 12.5.1		N/A
5.4.3.h)	Instructions relating to the handling, containment and exhaust of hazardous substances		N/A
5.4.3.i)	Any drainage systems required		N/A
5.4.3.j)	Protective measures relating to hazardous radiation		N/A
5.4.3.k)	Connections to the supply	DC9V,2.5A (via external approved adaptor) DC 7.4V (via Lithium-Ion rechargeable battery)	N/A
5.4.3.l)	PERMANENTLY CONNECTED EQUIPMENT only:		N/A
	1) Mains supply requirements and details of connections		N/A
	2) If external switch or circuit-breaker, requirements and location recommendation		N/A
5.4.3.m)	Special services including pressure limits		N/A
5.4.4	Equipment operation		P
	Instructions for use include:	See page 5 to 10 for following information.	P
5.4.4a)	Details of operating controls		P
5.4.4b)	Positioning for disconnection		P

IEC 61010-2-101 / EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
5.4.4c)	Interconnection		P
5.4.4d)	Specification of intermittent operation limits		N/A
5.4.4e)	Explanation of symbols used		P
5.4.4.f)	Any actions to be taken by an OPERATOR in case of a malfunction		N/A
5.4.4.g)	Cleaning and decontamination (see 11.2) incl. materials		N/A
5.4.4.h)	Disposal of waste	See paragraph 1 on page 3.	P
5.4.4.i)	Hazardous substances, use, need for training, or personal protection measures		N/A
5.4.4.j)	Infectious substances, need to use protective gloves or other protective means	See above.	P
5.4.4.k)	Hazardous vapours, instructions for protection of the mouth, nose or eyes		N/A
5.4.4.l)	Hazardous radiation, instructions and requirements for protective devices		N/A
5.4.4.m)	A statement about protection impairment if used in a manner not specified by the manufacturer		N/A
5.4.4.101	Self-test IVD medical equipment		N/A
	Instructions for use for self-test equipment comply with annex BB		N/A
5.4.101	Removal of equipment from use for repair or disposal		P
	Instructions for the RESPONSIBLE BODY for eliminating or reducing HAZARDS includes:	See paragraph 1 on page 3.	P
	Removal from use		P
	Transportation or disposal		P
	Requirements for minimizing biohazards		P
5.4.102	Transport and storage		P
	Permissible environmental conditions for transport and storage specified:	Installed in hard metal case mentioned in user manual.	P
	In documentation; and	See above	P
	On outside of packaging		P

8	MECHANICAL RESISTANCE TO SHOCK AND IMPACT		N/A
8.1.101	Transport and storage		N/A
	Records of tests performed by the manufacturer show conformity (Guidance ASTM D4169 of ISTA)	(See test records attached)	N/A

11	PROTECTION AGAINST HAZARDS FROM FLUIDS		N/A
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IEC 61010-2-101 / EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
11.3	Spillage		N/A
	Potentially aggressive substances (such as corrosive, toxic or flammable liquids) taken into account		N/A
	Potentially aggressive substances compatible with contacted parts of the equipment		N/A

13	PROTECTION AGAINST LIBERATED GASES AND SUBSTANCES, EXPLOSION AND IMPLOSION		N/A
13.1	Poisonous and injurious gases and substances		N/A
	Attached data/test reports demonstrate conformity (in NC and SFC)	(see Form A.1)	N/A
	Dangerous amounts of poisonous or injurious gases or substances not liberated in NORMAL CONDITION or in SINGLE FAULT CONDITION		N/A
	If potentially hazardous substances are liberated:		N/A
	OPERATOR not be wetted nor able to inhale quantities likely to be hazardous		N/A
	Protective covers or similar means of protection		N/A

14	COMPONENTS		N/A
14.3	Overtemperature protection devices		N/A
14.3 c)	Does not operate in NORMAL USE		N/A
	Not self-resetting in self-test IVD equipment		N/A

Annex AA	RISK MANAGEMENT		N/A
	EN ISO 14971 applied		N/A
	Conformity demonstrated	(see documents attached)	N/A
			N/A
	GROUP DEVIATIONS OF EN 61010-2-101: 2002		N/A
5.4.4	Equipment operation		N/A
	Instructions for IVD medical equipment for commercial use comply with EN 591	(see documents attached)	N/A
	Instructions for self-test IVD medical equipment use comply with EN 592	(see documents attached)	N/A
5.4.4.101	Self-test IVD medical equipment	Clause deleted	N/A

IEC 61010-2-101 / EN 61010-2-101				
Clause	Requirement + Test	Result - Remark		Verdict
4.4.2	TABLE: Summary of SINGLE FAULT CONDITIONS			Form A.1
				P
Subclause	Title	Does not apply	Carried out	Comments
4.4.2.1	PROTECTIVE IMPEDANCE	X		
4.4.2.2	Protective conductor	X		see Form A.8
4.4.2.3	Equipment or parts for short-term or intermittent operation	X		
4.4.2.4	Motors		X	DC motor inside printer only. See EN 61010-1 test report.
4.4.2.5	Capacitors	X		
4.4.2.6	Mains transformers Attach drawing of MAINS TxS showing all protective devices (see Forms A.29 and A.30)	X		
4.4.2.7	Outputs	X		
4.4.2.8	Equipment for more than one supply		X	See EN 61010-1 test report.
4.4.2.9	Cooling – air holes closed – fans stopped – coolant stopped	X		
4.4.2.10	Heating devices – timer overridden – temperature controller overridden – loss of cooling liquid – overfilled or empty or both	X		
4.4.2.11	Insulation between circuits and parts		X	See EN 61010-1 test report.
4.4.2.12	Interlocks	X		
4.4.2.101	Incorrect voltage selection	X		
List below all SINGLE FAULT CONDITIONS not covered by 4.4.2.1 to 4.4.2.101:				
13.1	Poisonous and injurious gases and substances	X		
NOTE – Record surface temperatures of flammable liquids and parts in contact with them in Form A.20A				
Supplementary information: (see Form A.2 for details of tests)				

Product:

Drug Test Analyzer

Type Designation:

WDTP-10

Photo-01 Front view



Photo-02 Rear view



Product:

Drug Test Analyzer

Type Designation:

WDTP-10

Photo-03 Top view



Photo-04 Side view



Product:

Drug Test Analyzer

Type Designation:

WDTP-10

Photo-05 Side view



Photo-06 Internal view



Photo-07 Scan parts view

Product:

Drug Test Analyzer

Type Designation:

WDTP-10



Photo-08 Internal view



Photo-09 Internal view

Product:

Drug Test Analyzer

Type Designation:

WDTP-10



Photo-10 Internal view



Photo-11 Internal view of print part

Product:

Drug Test Analyzer

Type Designation:

WDTP-10



Photo-12 Internal view of print part



Photo-13 Internal view of print part

Product:

Drug Test Analyzer

Type Designation:

WDTP-10



Photo-14 Battery top view



Photo-15 Battery bottom view

Product:

Drug Test Analyzer

Type Designation:

WDTP-10



Photo-16 External adaptor view

