Test Report issued under the responsibility of:
Dt&C Co., Ltd.

42, Yurim-ro, 154beon-gil, Cheoin-gu, Yongin-si,
Gyeonggi-do, 17042, Korea, Republic of

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

Report Number. .....:	DRMKCEL2303-0016
Date of issue .....:	2023-03-08
Total number of pages.....:	118 pages
Name of Testing Laboratory preparing the Report.....:	Dt&C Co., Ltd. 42, Yurim-ro, 154beon-gil, Cheoin-gu, Yongin-si, Gyeonggi-do, 17042, Korea, Republic of
Applicant's name .....:	Plasmapp Co., Ltd.
Address .....:	102, Cheombok-ro, Dong-gu, Daegu, 41061, Republic of Korea
Test specification:	
Standard.....:	IEC 61010-1:2010/AMD1:2016
Test procedure .....:	—
Non-standard test method .....:	N/A
TRF template used.....:	IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No. .....:	IEC61010_1P (Dt&C Co., Ltd.: TRF-MS-327(01)230203)
Test Report Form(s) Originator ....:	VDE Prüf- und Zertifizierungsinstitut GmbH (Dt&C modified on 2023-02-03)
Master TRF.....:	2021-04-12

This report is not valid as a CB Test Report unless signed by an approved IECEE Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.
This test report is related to KS Q ISO/IEC 17025 and KOLAS accreditation.

General disclaimer:

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

Test item description ..... :	Low temperature plasma sterilizer
Trade Mark ..... :	*plasmapp
Manufacturer ..... :	Plasmapp Co., Ltd. 102, Cheombok-ro, Dong-gu, Daegu, 41061, Republic of Korea
Model/Type reference ..... :	STERLINK mini
Ratings ..... :	(220-240) V~, (50/60) Hz, 1.5 kVA

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):

☒	**Testing Laboratory:**	Dt&C Co., Ltd.	
	Testing location/ address ..... :	42, Yurim-ro, 154beon-gil, Cheoin-gu, Yongin-si, Gyeonggi-do, 17042, Korea, Republic of	
	Tested by (name, function, signature) ..... :	MyeongSang You	
	Approved by (name, function, signature) .. :	HanJin Lee	
☐	**Testing procedure: CTF Stage 1:**		
	Testing location/ address ..... :		
	Tested by (name, function, signature) ..... :		
	Approved by (name, function, signature) .. :		
☐	**Testing procedure: CTF Stage 2:**		
	Testing location/ address ..... :		
	Tested by (name + signature) ..... :		
	Witnessed by (name, function, signature) . :		
	Approved by (name, function, signature) .. :		
☐	**Testing procedure: CTF Stage 3:**		
☐	**Testing procedure: CTF Stage 4:**		
	Testing location/ address ..... :		
	Tested by (name, function, signature) ..... :		
	Witnessed by (name, function, signature) . :		
	Approved by (name, function, signature) .. :		
	Supervised by (name, function, signature) :		

List of Attachments (including a total number of pages in each attachment)		
Document No.	Documents included / attached to this report (description)	Page No.
Attachment 1	Photographs	12
Attachment A	IEC 61010-2-040:2020	32

Documents referenced by this report (available on request): N/A		
Document Name or No.	Documents description	Page No.

Summary of testing:

- Maximum ambient temperature recommended by manufacturer: 40 ℃
- Max. normal condition: Sterilize mode, continuous operating
- Main power supply cord is detachable power cord use.

Clause	Comment

Test Report History: N/A
This report may consist of more than one report and is only valid with additional or previous issued reports:

Report Ref. No.	Item

Tests performed (name of test and test clause):

- Input Test (Clause 5.1.3 c))
- Marking Durability Test (Clause 5.3)
- Capacitor Test (Clauses 6.1.2 and 6.3.1 c))
- Determination of ACCESSIBLE parts (Clauses 6.2 and 6.3)
- Values in NORMAL CONDITION (Clause 6.3.1)
- Values in SINGLE FAULT CONDITION (Clause 6.3.2)
- Cross-sectional area of bonding conductors (Clause 6.5.2.2)
- Tightening torque test (Clause 6.5.2.3)
- Bonding impedance of plug connected equipment (Clause 6.5.2.4)
- Clearances and Creepage Distances Measurement (Clause 6.7)
- Dielectric Strength Tests (Clauses 6.7 and 6.8)
- Humidity Preconditioning (Clause 6.8.2)
- Cord anchorage (Clause 6.10.2)
- Stability Test (Clause 7.4)
- Enclosure Rigidity Test (Clauses 8.2.1, 8.2.2 and 6.8.3)
- Drop Test (Clause 8.3 and 6.8.4)
- Single Fault Conditions Test (Clauses 4.4 and 6.8.4)
- Protection against the spread of fire (Clause 9)
- Single fault conditions test (Clause 9.1 a), 4.4 and 6.8)
- Temperature Measurement Test (Clauses 10.1 to 10.4.2)
- Resistance to heat of non-metallic ENCLOSURES (Clause 10.5.2)
- Insulating Materials (Clause 10.5.3)
- Protection Against Hazardous From Fluids (Clauses 11.2, 6.8 and 6.3.1)
- Batteries and battery charging (Clause 13.2.2)

Testing location:

☒ Permanent Testing Lab ☐ On Site Testing

Dt&C Co., Ltd.

(Satellite facilities-1) 46, Yurim-ro, 154beon-gil, Cheoin-gu, Yongin-si, Gyeonggi-do, 17042, Korea, Republic of

Summary of compliance with National Differences (List of countries addressed):

N/A

☐ **The product fulfils the requirements of _____ (insert standard number and edition and delete the text in parenthesis or delete the whole sentence if not applicable)**

Statement concerning the uncertainty of the measurement systems used for the tests

(may be required by the product standard or client)

☐ **Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:**

Procedure number, issue date and title:

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

☒ **Statement not required by the standard used for type testing**

(Note: When IEC or ISO standard requires a statement concerning the uncertainty of the measurement systems used for tests, this should be reported above. The informative text in parenthesis should be delete in both cases after selecting the applicable option)

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.

<Main Label>

Test item particulars:	
Type of item ..... :	Laboratory
Description of equipment function..... :	To provide low temperature sterilization for medical devices
Connection to MAINS supply ..... :	Detachable cord set
Overvoltage category..... :	II
POLLUTION DEGREE..... :	2
Means of protection..... :	Class I (PE connected)
Environmental conditions ..... :	Normal
For use in wet locations..... :	No
Equipment mobility..... :	Floor standing
Operating conditions..... :	Continuous
Overall size of equipment (W x D x H)..... :	Main unit, Pump module: 275 mm (W) x 440 mm (D) x 330 mm (H)
Mass of equipment (kg)..... :	Main unit: 20.0 kg, Pump module: 21 kg
Marked degree of protection to IEC 60529 ..... :	IPX0
Possible test case verdicts:	
- Test case does not apply to the test object .....:	N/A (Not Applicable)
- Test object does meet the requirement.....:	P (Pass)
- Test object does not meet the requirement .....:	F (Fail)
Testing:	
Date of receipt of test item.....:	2022-11-29
Date (s) of performance of tests .....:	2022-11-29 to 2023-02-28

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 Forms 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 4.2.5 of IECEE 02:

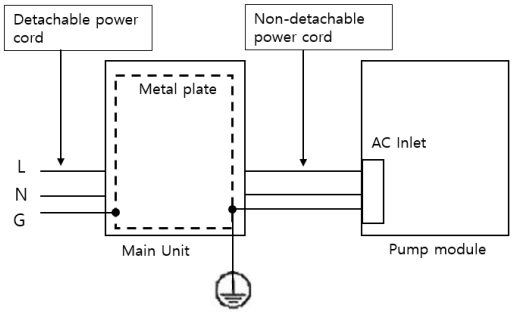
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided..... :	☐ **Yes** ☒ **Not applicable**

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

Name and address of factory (ies) .....:	Plasmapp Co., Ltd. 102, Cheombok-ro, Dong-gu, Daegu, 41061, Republic of Korea

General product information and other remarks:

- The STERLINK MINI sterilization system is a low temperature plasma sterilizer to inactivate microorganisms for a broad range of metal and nonmetal medical devices and surgical instruments at low temperature. This sterilizer offers an effective, safe, fast, economical, easy-to-use, reliable, and flexible sterilization method.
- Description of unit:
  1) This equipment is classified as Class I and Detachable cord set.
  2) To provide low temperature sterilization for medical devices
  3) Printers and printer adapters on this equipment are optional
  4) Max. operating condition: Sterilize mode, continuous operating
  5) Operating & Storage environment condition
     • Temperature: (10 to 40) ℃
     • Humidity: (30 to 85) % R.H.
     • Air pressure: (70 to 106) kPa
  6) Refer to User's Manual (Doc. No.: PLA-UM-SMC-001, Rev. 00)
- The equipment is constructed Main Unit and Pump module.
- The equipment connection to main supply: (See below)



- The above test report is the accredited test result by Korea Laboratory Accreditation Scheme, which signed the ILAC-MRA. The equipment fulfils the requirements of standards IEC 61010-1 (3.1 Edition), IEC 61010-2-040:2020

- This laboratory is not accredited for the test results marked " * "
  12.3 UV Radiation
  12.6 Laser Source
  13.2.3 Implosion of cathode ray tubes

Description of model differences:

N/A

Description of special features: N/A
(HV circuits, high pressure systems etc.)

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
4	**TESTS**		—
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)	P
4.4.2.2	PROTECTIVE IMPEDANCE	No protective impedance	N/A
4.4.2.3	PROTECTIVE CONDUCTOR	(See Form A.1 and 26A)	P
4.4.2.4	Equipment or parts for short-term or intermittent operation	Continuous operation	N/A
4.4.2.5	Motors	No motors	—
	– stopped while fully energized		N/A
	– prevented from starting		N/A
	– one phase interrupted (multi-phase)		N/A
4.4.2.6	Capacitors	No motors capacitors	N/A
4.4.2.7	MAINS transformers	Approved SMPS used	N/A
4.4.2.7.2	Short circuit	(See above)	N/A
4.4.2.7.3	Overload	(See above)	N/A
4.4.2.8	Outputs	(See Form A.1 and 26A)	P
4.4.2.9	Equipment for more than one supply		N/A
4.4.2.10	Cooling	(See Form A.1 and 26A)	—
	– air holes closed		P
	– fans stopped		P
	– coolant stopped		N/A
	– loss of cooling liquid		N/A
4.4.2.11	Heating devices		—
	– timer overridden		P
	– temperature controller overridden		P
4.4.2.12	Insulation between circuits and parts		N/A
4.4.2.13	Interlocks		P
4.4.2.14	Voltage selectors	No such 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 and A.18)	P
5	**MARKING AND DOCUMENTATION**		—
5.1	**Marking**		P
5.1.1	General		P
	Required equipment markings		—

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Visible from the exterior; or		P
	– Visible after removing cover or opening door		P
	– Visible after removal from a rack or panel	No rack mounted unit	N/A
	Not put on parts which can be removed by an operator	No part which can be removed by an operator	P
	Letter symbols (IEC 60027) used		P
	Graphic symbols of Table 1 used	Used symbol of Table 1 (2, 6, 9, 10, 12, 13, 14)	P
5.1.2	Identification		P
	Equipment is identified by:		—
	a) Manufacturer's or supplier's name or trademark	Plasmapp Co., Ltd.	P
	b) Model number, name or other means	STERLINK mini	P
	Manufacturing location identified	Only one factory location	N/A
5.1.3	MAINS supply		P
	Equipment is marked as follows:		—
	a) Nature of supply:		—
	1) a.c. RATED MAINS frequency or range of frequencies .....:	(50/60) Hz	—
	2) d.c. with symbol 1.....:	-	—
	b) RATED supply voltage(s) or range .....:	(220-240) V~	—
	c) Max. RATED power (W or VA) or input current .....:	1.5 kVA	—
	The marked value not less than 90 % of the maximum value	(See Form A.2)	P
	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:		—
	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:		—
	With the voltage if it is different from the MAINS supply voltage.....:		—
	For use only with specific equipment		N/A
	If not marked for specific equipment it is marked with:		—
	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		P
	OPERATOR replaceable fuse marking (see also 5.4.5).....:	250 V~, T10.0 AL (Appliance inlet fuse)	—
5.1.5	TERMINALS, connections and operating devices		P
5.1.5.1	General		—
	Where necessary for safety, indication of purpose of TERMINALS, connectors, controls and indicators marked	Marked	P
	If insufficient space, symbol 14 used		N/A
	Push-buttons and actuators of emergency stop devices and indicators:	No emergency stop switch	—
	– 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):		—
	– to safety of persons; or		N/A
	– safety of the environment		N/A
5.1.5.2	TERMINALS		—
	MAINS supply TERMINAL identified		P
	Other TERMINAL marking:		—
	a) FUNCTIONAL EARTH TERMINALS marked with symbol 5	No functional earth terminals	N/A
	b) PROTECTIVE CONDUCTOR TERMINALS:	(See below)	—
	Symbol 6 is placed close to or on the TERMINAL; or	Marked "⏚" near protective earth terminal	P
	Part of appliance inlet		N/A
	c) TERMINALS of circuits (symbol 7 used)	No such terminals	N/A
	d) HAZARDOUS LIVE TERMINALS supplied from the interior		N/A
	Standard MAINS socket outlet used; or		N/A
	RATINGS marked; or		N/A
	Symbol 14 used		N/A
5.1.6	Switches and circuit-breakers	Main Switch used	P
	If disconnecting device, off position clearly marked	Symbol 9, 10 in the Table 1	P
	If push-button used as power supply switch:		—
	– 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		P
	Protected throughout (symbol 11 used)		N/A
	Only partially protected (symbol 11 not used)	Class I equipment	P
5.1.8	Field-wiring TERMINAL boxes	No field wiring terminals.	N/A
	If TERMINAL or ENCLOSURE exceeds 60 °C:		—
	Cable temperature RATING marked ..... :		—
	Marking visible before and during connection or beside TERMINAL		N/A
5.2	**Warning markings**		P
	Visible when ready for NORMAL USE	Cleary visible	P
	Are near or on applicable parts	Marked on applicable parts	P
	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		P
	b) Symbols and text moulded, stamped or engraved in material min. 2,0 mm high and	No such parts	N/A
	0,5 mm depth or raised if not contrasting in colour		N/A
	If necessary marked with symbol 14, or	Marked on Adhesive label	P
	Additional symbols such as symbol 12, 13 or 17 used to indicate the nature of HAZARD	(See Above)	P
	Statement to place equipment in a safe state before access by using a tool to HAZARDOUS parts is permitted	No such part	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		N/A
	Documentation necessary for safe operation is provided in printed media or		P
	in electronic media if available at any time		N/A
	Documentation includes:		—
	a) Intended use	Refer to User manual	P
	b) Technical specification	Refer to User manual	P
	c) Name and address of manufacturer or supplier	Refer to User manual	P

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	d) Information specified in 5.4.2 to 5.4.6	Refer to User manual	P
	e) Information to mitigate residual RISK (see also subclause 17)		N/A
	f) Accessories for safe operation of the equipment specified	Refer to 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		N/A
	h) Instructions for lifting and carrying	Refer to User manual	P
	Warning statements and a clear explanation of warning symbols:		—
	– provided in the documentation; or		P
	– information is marked on the equipment		N/A
5.4.2	Equipment RATINGS		P
	Documentation includes:		—
	a) Supply voltage or voltage range..... :	(220-240) V~	—
	Frequency or frequency range ..... :	(50/60) Hz	—
	Power or current rating..... :	1.5 kVA	—
	b) Description of all input and output connections in accordance to 6.6.1 a)	Refer to User manual	P
	c) RATING of insulation of external circuits in accordance to 6.6.1 b)		N/A
	d) Statement of the range of environmental conditions (refer to 1.4):		
	1) indoor or outdoor use,		P
	2) altitude,		P
	3) temperature,		P
	4) relative humidity,		P
	5) MAINS supply voltage fluctuations,		P
	6) OVERVOLTAGE CATEGORY,		N/A
	7) WET LOCATION, if applicable,		N/A
	8) POLLUTION DEGREE of the intended environment		P
	e) Degree of ingress protection (IEC 60529)	IPX0	N/A
	f) If impact rating less than 5 J:		—
	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:		—

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Assembly, location and mounting requirements	Refer to User manual	P
	b) Instructions for protective earthing	Refer to User manual	P
	c) Connections to supply	Refer to User manual	P
	d) PERMANENTLY CONNECTED EQUIPMENT:	Not permanently equipment	—
	1) Supply wiring requirements		N/A
	2) If external switch or circuit-breaker, requirements and location recommendation		N/A
	e) Ventilation requirements	Refer to User manual	P
	f) Safety characteristics for special external services (e. g. maximum and minimum temperature, pressure, flow of air, cooling liquid)	No special services	N/A
	g) Instructions relating to sound level	No sound power	N/A
5.4.4	Equipment operation		P
	Instructions for use include:		—
	a) Identification and description of operating controls	Refer to User manual	P
	b) Positioning for disconnection	Refer to User manual	P
	c) Instructions for interconnection to accessories or other equipment	Refer to User manual	P
	d) Specification of intermittent operation limits	Continuous operation	N/A
	e) Explanation of symbols used	Refer to User manual	P
	f) Replacement of consumable materials	Refer to User manual	P
	g) Cleaning and decontamination	Refer to User manual	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 c)	No flammable liquids provided	N/A
	j) RISK reduction procedures relating burn from surfaces permitted to exceed limits of 10.1	No such parts	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		P
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:		—
	Instruction against the use of detachable MAINS supply cord with inadequate RATING	Refer to User manual	P
	Specific battery type of user replaceable batteries		N/A
	Any manufacturer specified parts	No such parts	N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RATING and characteristics of fuses	250 V~, T10.0 AL (Appliance inlet fuse)	P
	Instructions include following subjects permitting safe servicing and continued safety:		—
	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
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**		—
6.1	**General**	(see Form A.14 and A.15)	P
6.1.1	Requirements		P
	Protection against electric shock maintained in NORMAL CONDITION and SINGLE FAULT CONDITION		P
	ACCESSIBLE parts not HAZARDOUS LIVE	No hazardous live	P
	Voltage, current, charge or energy below the limits in NORMAL CONDITION and in SINGLE FAULT CONDITION between:		—
	ACCESSIBLE parts and earth		P
	two ACCESSIBLE parts on same piece of the equipment within a distance of 1,8 m		P
	Conformity is checked by the determination of 6.2 and 6.3 followed by the tests of 6.4 to 6.11		P
6.1.2	Exceptions	No exceptions.	N/A
	Following HAZARDOUS LIVE parts may be ACCESSIBLE to an OPERATOR:		—
	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.4)	P
6.2.1	General		P
	Unless obviously determination of ACCESSIBLE parts as specified in 6.2.2 to 6.2.4	(See 6.2.2 to 6.2.4)	P
6.2.2	Examination		P
	– with jointed test finger (as specified B.2)		P

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– with rigid test finger (as specified B.1) and a force of 10 N		P
6.2.3	Openings above parts that are HAZARDOUS LIVE	No openings	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
	– test pin with length of 100 mm and 3 mm in diameter applied	No openings for pre-set controls	N/A
6.3	**Limit values for ACCESSIBLE parts**		P
6.3.1	Levels in NORMAL CONDITION	(see Form A.5)	P
	a) Voltage limits less than 30 V r.m.s. and 42,4 V peak or 60 V d.c.		P
	for WET LOCATIONS voltage limits less than 16 V r.m.s. and 22,6 V peak or 35 V d.c.	Not intended for use in wet locations	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
	c) Levels of capacitive charge or energy less:		—
	1) 45 µC 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	(see Form A.6)	P
	a) Voltage limits less than 50 V r.m.s. and 70 V peak or 120 V d.c.		P
	for WET LOCATIONS voltage limits less than 33 V r.m.s. and 46,7 V peak or 70 V d.c.	Not intended for use in wet locations	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	Not intended for use in wet locations	N/A
	500 mA r.m.s. when measured with circuit A.3 for higher frequencies		N/A
	c) Levels of capacitive charge or energy less line B of Figure 3		N/A
6.4	**Primary means of protection**		P

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
6.4.1	General		P
	ACCESSIBLE parts prevented from being HAZARDOUS LIVE by one or more of following means:		—
	a) ENCLOSURES or PROTECTIVE BARRIERS (see 6.4.2)		P
	b) BASIC INSULATION (see 6.4.3)		P
	c) Impedance (see 6.4.4)	No protective impedance	N/A
6.4.2	ENCLOSURES or PROTECTIVE BARRIERS	(see Form A.15 and A.16)	P
	– meet rigidity requirements of 8.1		P
	– meet requirements for BASIC INSULATION, if protection is provided by insulation		P
	– meet requirements of 6.7 for CREEPAGE and – CLEARANCES between ACCESSIBLE parts and – HAZARDOUS live parts, if protection is provided by – limited access		P
6.4.3	BASIC INSULATION	(see Form A.15 and A.16)	P
	– meet CLEARANCE, CREEPAGE DISTANCE and solid insulation requirements of 6.7		P
6.4.4	Impedance	No protective impedance	N/A
	Impedance used as primary means of protection meets all the 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**		P
6.5.1	General		P
	ACCESSIBLE parts are prevented from becoming HAZARDOUS live by the primary means of protection and supplemented by one of:		—
	a) PROTECTIVE BONDING (see 6.5.2)		P
	b) SUPPLEMENTARY INSULATION (see 6.5.3)		N/A
	c) automatic disconnection of the supply (see 6.5.5)	No automatic disconnection	N/A
	d) current- or voltage-limiting device (see 6.5.6)	No such device	N/A
	Alternatively one of the single means of protection is used:		—
	e) REINFORCED INSULATION (see 6.5.3)		P
	f) PROTECTIVE IMPEDANCE (see 6.5.4)	No protective impedance	N/A
6.5.2	PROTECTIVE BONDING	(see Form A.7, A.8, A.9)	P
6.5.2.1	General		P

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ACCESSIBLE conductive parts, may become HAZARDOUS LIVE in SINGLE FAULT CONDITION:		—
	Bonded to the PROTECTIVE CONDUCTOR TERMINAL; or		P
	Separated by conductive screen or barrier bonded to PROTECTIVE CONDUCTOR TERMINAL	No screen or barrier bonded to PE terminal	N/A
6.5.2.2	Integrity of PROTECTIVE BONDING		—
	a) PROTECTIVE BONDING consists of directly connected structural parts or discrete conductors or both; and withstands thermal and dynamic stresses	Single connection	P
	b) Soldered connections:	No soldered connections	—
	Independently secured against loosening		N/A
	Not used for other purposes		N/A
	c) Screw connections are secured		P
	d) PROTECTIVE BONDING not interrupted; or		P
	except as removable part that carries MAINS SUPPLY input connection to the whole equipment		P
	e) Any movable PROTECTIVE BONDING connection specifically designed, and meets 6.5.2.4	No moveable conductive connector	N/A
	f) No external metal braid of cables used (not regarded as PROTECTIVE BONDING)	No external metal braid of cables	N/A
	g) IF MAINS SUPPLY passes through:		—
	Means provided for passing protective conductor;	No main supply connection for other equipment	N/A
	Impedance meets 6.5.2.4		N/A
	h) Protective conductors bare or insulated, if insulated, green/yellow	Green / Yellow	P
	Exceptions:		—
	1) earthing braids;		N/A
	2) internal protective conductors etc.;		N/A
	Green/yellow not used for other purposes	Not used for other purposes	P
	TERMINAL suitable for connection of a PROTECTIVE CONDUCTOR, and meets 6.5.2.3	(See clause 6.5.2.3)	P
6.5.2.3	PROTECTIVE CONDUCTOR TERMINAL		—
	a) Contact surfaces are metal		P
	b) Appliance inlet used		N/A
	c) For rewirable cords and PERMANENTLY CONNECTED EQUIPMENT, PROTECTIVE CONDUCTOR TERMINAL is close to MAINS supply TERMINALS	No permanently connected equipment	N/A
	d) If no MAINS supply is required, any PROTECTIVE CONDUCTOR TERMINAL:		—
	Is near terminals of circuit for which protective earthing is necessary		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	External if other terminals external		N/A
	e) Equivalent current-carrying capacity to MAINS supply TERMINALS	(see Form A.7)	P
	f) If plug-in, makes first and breaks last		P
	g) If also used for other bonding purposes, PROTECTIVE CONDUCTOR:	No PE connection for other bonding purposes	—
	Applied first;		N/A
	Secured independently;		N/A
	Unlikely to be removed by servicing		N/A
	h) PROTECTIVE CONDUCTOR of measuring circuit:	No measuring circuit	—
	1) Current RATING equivalent to measuring circuit TERMINAL;		N/A
	2) PROTECTIVE BONDING: not interrupted by any switch or interrupting device		N/A
	i) FUNCTIONAL EARTH TERMINALS allow independent connection	No functional earth terminals	N/A
	j) If a binding screw used for PROTECTIVE CONDUCTOR TERMINAL:		—
	Suitable size for bond wire		P
	Not smaller than M 4		P
	At least 3 turns of screw engaged		P
	Passes tightening torque test	(see Form A.8)	P
	k) Contact pressure not capable being reduced by deformation of materials		P
6.5.2.4	Impedance of PROTECTIVE BONDING of plug-connected equipment	(see Form A.9)	P
	Impedance between PROTECTIVE CONDUCTOR TERMINAL and each ACCESSIBLE part where PROTECTIVE BONDING is specified, is:		—
	– less than 0,1 Ohm; or		P
	– less than 0,2 Ohm if equipment is provided with non-detachable cord		N/A
6.5.2.5	Impedance of PROTECTIVE BONDING of PERMANENTLY CONNECTED EQUIPMENT	Not permanently connected equipment.	N/A
6.5.2.6	Transformer PROTECTIVE BONDING screen	No such parts	N/A
	Transformer provided with screen for PROTECTIVE BONDING:		—
	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:		—

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Independently secured against loosening		N/A
	– Not used for other purposes		N/A
6.5.3	SUPPLEMENTARY and REINFORCED INSULATION		P
	Meet CLEARANCE, CREEPAGE DISTANCE and solid insulation requirements of 6.7		P
6.5.4	PROTECTIVE IMPEDANCE	No 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:		—
	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 part	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	No such devices	N/A
	Device complies with all of:		—
	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**		P
6.6.1	General		P
	Connections do not cause ACCESSIBLE parts of the following to become HAZARDOUS LIVE in NORMAL CONDITION or SINGLE FAULT CONDITION:		—
	– the external circuits		N/A
	– the equipment	External printer (Option)	P

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Protection achieved by separation of circuits; or		N/A
	short circuit of separation does not cause a HAZARD		P
	Instructions or markings for each terminal include:		—
	a) RATED conditions for TERMINAL	Refer to User manual	P
	b) Required RATING of external circuit insulation		N/A
6.6.2	TERMINALS for external circuits	No 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:		—
	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	Terminals for stranded conductors	No stranded conductors	N/A
	No RISK of accidental contact because:		—
	– Located or shielded		N/A
	– Self-evident or marked whether or not connected to ACCESSIBLE conductive parts		N/A
	Complies as applicable:		—
	a) Manufacturer's specified maximum length of removed insulation, or		N/A
	b) 8 mm length of insulation removed		N/A
6.7	**Insulation requirements**	(see Form A.14)	P
6.7.1	The nature of insulation		P
6.7.1.1	General		P
	Insulation between ACCESSIBLE parts or between separate circuits consist of CLEARANCES, CREEPAGE DISTANCES and solid insulation if provided as protection against a HAZARD		P
6.7.1.2	CLEARANCES		P
	Required CLEARANCES reflecting factors of 6.7.1.1	(see Form A.14 and A.15)	P
	Equipment rated for operating altitude greater than 2000 m correction factor of Table 3 of 61010-1 applied	< 2 000 m	N/A
6.7.1.3	CREEPAGE DISTANCES		P
	Required CREEPAGE DISTANCES reflecting factors of 6.7.1.1 a) to d)	(see Form A.14 and A.15)	P
	CTI material group reflected by requirements	Material group: IIIb	P
	CTI test performed		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
6.7.1.4	Solid insulation		P
	Required solid insulation reflecting factors of 6.7.1.1 a) to d)	(see Form A.14 and A.15)	P
6.7.1.5	Requirements for insulation according to type of circuit	(see Form A.14 and A.15)	P
	a) 6.7.2 MAINS circuits of OVERVOLTAGE CATEGORY II up to nominal supply voltage of 300 V		P
	b) 6.7.3 secondary circuits separated from circuits defined in a) by transformer		N/A
	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:		—
	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		P
6.7.2.1	CLEARANCES and CREEPAGE DISTANCES	(see Forms A.14 and A.15)	—
	Values for MAINS CIRCUITS of Table 4 are met		P
	Coatings to achieve reduction to POLLUTION DEGREE 1 comply with requirements of Annex H	Pollution degree 2	N/A
6.7.2.2	Solid insulation		P
6.7.2.2.1	General		P
	Withstands electrical and mechanical stresses in normal use and all RATED environmental conditions of 1.4		P
	Equipment passed voltage tests of 6.8.3 with values of Table 5	(see Form A.18)	P
	Complies as applicable:		—
	a) ENCLOSURE or PROTECTIVE BARRIER of Clause 8	Enclosure complies with the rigidity requirements of clause 8	P
	b) moulded and potted parts requirements of 6.7.2.2.2		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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		—
	Conductors between same two layers are separated by at least 0,4 mm after moulding is completed	No such parts	N/A
6.7.2.2.3	Inner insulating layers of printed wiring boards		—
	Separated by at least 0,4 mm between same two layers		N/A
	REINFORCED INSULATION has adequate electric strength; one of following methods used:		—
	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		—
	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 the following methods used:		—
	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	No such insulation relied upon	N/A
6.7.3.1	General		N/A
	Secondary circuits where separation from MAINS CIRCUITS is achieved by a transformer providing:		—
	– 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	No such insulation relied upon	N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	twice the values of Table 6 for REINFORCED INSULATION; or		N/A
	b) pass the voltage tests of 6.8 with values of Table 6;		N/A
	with following adjustments:		—
	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
	Based on WORKING VOLTAGE meets the values of Table 7 for BASIC and SUPPLEMENTARY INSULATION	No such insulation relied upon	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	General	No such insulation relied upon	N/A
	Withstands electrical and mechanical stresses in normal use and all RATED environmental conditions of 1.4		—
	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:		—
	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		—
	Conductors between same two layers are separated by applicable distances of Table 8	No such insulation relied upon	N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
6.7.3.4.3	Inner insulation layers of printed wiring boards		—
	Separated by at least the applicable distances of Table 8 between same two layers	No such insulation relied upon	N/A
	REINFORCED INSULATION have adequate electric strength; one of following methods used:		—
	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		—
	Conductors between same two layers are separated by applicable CLEARANCES and CREEPAGE DISTANCE of 6.7.3.2 and 6.7.3.3	No such insulation relied upon	N/A
	REINFORCED INSULATION have adequate electric strength; one of following methods used:		—
	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:		—
	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 voltage tests**	(see Form A.14 and A.18)	P
6.9	**Constructional requirements for protection against electric shock**		P
6.9.1	General		P
	If a failure could cause a HAZARD:		—
	a) security of wiring connections	Not depend on soldering	P
	b) screws securing removable covers	Used Screws in cover	P
	c) accidental loosening		P
	d) CLEARANCES and CREEPAGE DISTANCES not reduced below the values of basic insulation by loosening of parts or wires	Not reduced	P
6.9.2	Insulating materials		P
	Material not to be used for safety relevant insulation:		—
	a) easily damaged materials not used	Certified insulating materials used	P

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	b) non-impregnated hygroscopic materials not used	Non-impregnated hygroscopic materials not used	N/A
6.9.3	Colour coding		P
	Green-and-yellow insulation shall not be used except:		—
	a) protective earth conductors;	Green / Yellow	P
	b) PROTECTIVE BONDING conductors;	Green / Yellow	P
	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**		P
6.10.1	MAINS supply cords		P
	RATED for maximum equipment current (see 5.1.3 c)		P
	Cable complies with IEC 60227 or IEC 60245	(see TABLE 1.A)	P
	Heat-resistant if likely to contact hot parts	No such parts	N/A
	Temperature RATING (cord and inlet) .....:		—
	Green/yellow used only for connection to PROTECTIVE CONDUCTOR TERMINALS	Green / Yellow	P
	Detachable cords with IEC 60320 MAINS connectors:		—
	Conform to IEC 60799; or		P
	Have the current RATING of the MAINS connector		P
6.10.2	Fitting of non-detachable MAINS supply cords	Non-detachable cord used (Between Main Unit and Pump module) (see TABLE A.19)	P
6.10.2.1	Cord entry		—
	a) inlet or bushing with a smoothly rounded opening; or		P
	b) insulated cord guard protruding >5 D (diameter)		N/A
6.10.2.2	Cord anchorage		—
	Protective earth conductor is the last to take the strain		P
	a) cord is not clamped by direct pressure from a screw		P
	b) knots are not used		P
	c) cannot push the cord into the equipment to cause a HAZARD		P
	d) no failure of cord insulation in anchorage with metal parts		P
	e) not to be loosened without a tool		P
	f) cord replacement does not cause a HAZARD and method of strain relief is clear		P
	Push-pull and or torque test	(see Form A.19)	P

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
6.10.3	Plugs and connectors		P
	MAINS supply plugs, connectors etc., conform with relevant specifications		P
	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		P
	MAINS type plugs used only for connection to MAINS supply		P
	Plug pins which receive a charge from an internal capacitor	(see Form A.5)	P
	Accessory MAINS socket outlets:	No 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**		P
6.11.1	Disconnects all current-carrying conductors		P
6.11.2	Exceptions		N/A
6.11.3	Requirements according to type of equipment		P
6.11.3.1	PERMANENTLY CONNECTED EQUIPMENT and multi-phase equipment	Not permanently connected 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		P
	Equipment is provided with one of the following:		—
	a) switch or circuit-breaker	Main switch used	P
	b) appliance coupler (disconnectable without tool)	Appliance coupler used	P
	c) separable plug (without locking device)		P
6.11.4	Disconnecting devices		P
6.11.4.1	General		P
	Disconnecting device part of equipment		P
	Electrically close to the SUPPLY		P
	Power-consuming components not electrically located between the supply source and the disconnecting device		P

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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		P
	When used as disconnection device:		—
	Circuit breaker meets the relevant requirements IEC 60947-2 and is suitable for the application		P
	Switch meets the relevant requirements IEC 60947-3 and is suitable for the application		—
	Marked to indicate function .....:	Used symbol 9, 10 of Table 1	—
	Not incorporated in MAINS cord		P
	Does not interrupt PROTECTIVE EARTH CONDUCTOR		P
6.11.4.3	Appliance couplers and plugs		P
	Where an appliance coupler or separable plug is used as the disconnecting device (see 6.11.3.2):		—
	Readily identifiable and easily reached by the operator		P
	Single-phase portable equipment cord length not more than 3 m		P
	PROTECTIVE EARTH CONDUCTOR connected first and disconnected last		P
7	**PROTECTION AGAINST MECHANICAL HAZARDS**		—
7.1	**General**		P
	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**		P
	Easily-touched parts are smooth and rounded	No hazards	P
	Do not cause injury during NORMAL USE and		P
	Do not cause injury during SINGLE FAULT CONDITION		P
7.3	**Moving parts**		P
7.3.1	General		P
	HAZARDS from moving parts limited to a tolerable level with the conditions specified in 7.3.2 and 7.3.5		P
	RISK assessment in accordance with 7.3.3 carried out		N/A
7.3.2	Exceptions		P
	Access to HAZARDOUS moving parts permitted under following circumstances:		—
	a) obviously intended to operate on parts or materials external of the equipment	No such parts	N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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:		—
	1) access requires TOOL	Refer to User manual	P
	2) statement about training in the instructions	Refer to User manual	P
	3) warning markings on covers prohibiting access by untrained OPERATORS	(See below)	P
	or symbol 14 with full details in documentation	Used symbol 14 of Table 1	P
7.3.3	RISK assessment for mechanical HAZARDS to body parts	No such 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	No such parts	N/A
	Following levels are met in NORMAL and SINGLE FAULT CONDITION:		—
	Continuous contact pressure below 50 N / cm² with force below 150 N		N/A
	Temporary force below 250 N for an area at least of 3 cm² for a maximum duration of 0,75 s		N/A
7.3.5	Gap limitations between moving parts		N/A
7.3.5.1	Access normally allowed	No moving parts	—
	If levels of 7.3.4 exceeded and a 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	No moving parts	—
	Maximum gap as specified in Table 14 assured in NORMAL and in SINGLE FAULT CONDITION		N/A
7.4	**Stability**		P
	Equipment not secured to building structure is physical stable		P
	Stability maintained after opening of drawers etc. by automatic means, or		N/A
	warning marking requires the application of means		P
	Compliance checked by following tests as applicable:	(see Form A.20A)	—
	a) 10° tilt test for other than handheld equipment	Not overbalance	P
	b) multi-directional force test for equipment exceeds height of 1 m and mass of 25 kg	Not exceed height of 1 m	N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) downward force test for floor-standing equipment	No floor-standing equipment	N/A
	d) overload test with 4 times maximum load for castor or support foot that supports greatest load, or	No such castor	N/A
	e) castor or support foot that supports greatest load removed from equipment	No such castor	N/A
7.5	**Provisions for lifting and carrying**		P
7.5.1	General		P
	Equipment more than 18 kg.....:	41 kg (Main unit with Pump module)	P
	Has means for lifting or carrying; or		N/A
	Directions are given in documentation	Refer to User manual	P
7.5.2	Handles and grips		—
	Handles or grips withstand four times weight	No such handles and grips	N/A
7.5.3	Lifting devices and supporting parts		—
	RATED for maximum load; or	No lifting devices and supporting parts	N/A
	Tested with four times maximum static load		N/A
7.6	**Wall mounting**	No wall mounting	N/A
	Mounting brackets withstand four times weight		N/A
	One fastener removed and test repeated with two times weight		N/A
7.7	**Expelled parts**	No 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**		—
8.1	**General**		P
	Equipment does not cause a HAZARD when subjected to mechanical stresses in NORMAL USE		P
	Normal protection level is 5 J	Considered 5 J	P
	Levels below 5 J but not less than 1 J are acceptable if all of the following criteria are met:		—
	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

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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:	(see Form A.16)	—
	1) Static test of 8.2.1	(See Clause 8.2.1)	P
	2) Impact test of 8.2.2 with 5 J except for HAND-HELD EQUIPMENT	(See Clause 8.2.2)	P
	if specified impact energy is not 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 and equipment with mass over 100 kg		P
	Equipment RATED with an impact rating of IK 08 that obviously meets the criteria		P
	After the tests inspection with following results:		—
	– HAZARDOUS LIVE parts above the limits of 6.3.2 not ACCESSIBLE		P
	– insulation pass the voltage tests of 6.8	(see Form A.30)	P
	i) No leaks of corrosive and harmful substances		N/A
	ii) ENCLOSURE shows no cracks resulting in a HAZARD		P
	iii) CLEARANCES not less than their permitted values		P
	iv) Insulation of internal wiring remains undamaged		P
	v) PROTECTIVE BARRIERS not damaged or loosened	No protective barriers	N/A
	vi) No moving parts exposed, except permitted by 7.3		P
	vii) No damage which could cause spread of fire		P
8.2	**ENCLOSURE rigidity test**		P
8.2.1	Static test	(see Form A.21A)	P
	– 30 N with 12 mm rod applied to each part of ENCLOSURE		P
	– in case of doubt test conducted at maximum RATED ambient temperature		P
8.2.2	Impact test	(see Form A.21A)	P
	Impact applied to any part of ENCLOSURE causing a HAZARD if damaged		P
	Impact energy level and corresponding IK code.....:	IK08	—
	Non-metallic ENCLOSURES cooled to minimum RATED ambient temperature if below 2 °C		N/A
8.3	**Drop test**		P
8.3.1	Other than HAND-HELD and DIRECT-PLUG-IN EQUIPMENT		P

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Tests conducted with a drop height or angle of .....:	(see Form A.21B)	—
8.3.2	HAND-HELD and DIRECT-PLUG-IN EQUIPMENT	No such parts	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**		—
9.1	**General**		P
	No spread of fire in NORMAL and SINGLE FAULT CONDITION		P
	MAINS supplied equipment meets requirements of 9.6 additionally	Overcurrent protection per clause 9.6 provided	P
	Conformity is checked by minimum one or a combination of the following (see Figure 11):	(see Form A.22)	—
	a) SINGLE FAULT test of 4.4; or	(see Form A.1)	P
	b) Application of 9.2 (eliminating or reducing the sources of ignition); or		N/A
	c) Application of 9.3 (containment of fire within the equipment)		P
9.2	**Eliminating or reducing the sources of ignition within the equipment**		N/A
	a) 1) Limited-energy circuit (see 9.4); or		N/A
	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
9.3.1	General		P
	Spread of fire outside equipment reduced to a tolerable level if:		—
	a) Energizing of the equipment is controlled by an OPERATOR held switch		N/A
	b) ENCLOSURE is conform with constructional requirements of 9.3.2; and	Enclosure is conform with constructional requirements of 9.3.2	P
	Requirements of 9.5 are met	No flammable liquids	N/A
9.3.2	Constructional requirements		P
	a) Connectors and insulating material have flammability classification V-2 or better	(see TABLE 1.A)	P

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	b) Insulated wires and cables are flame retardant (VW-1 or equivalent)	(see TABLE 1.A)	P
	c) ENCLOSURE meets following requirements:	(see Form A.22)	—
	1) Bottom and sides in arc of 5 ° (see Figure 13) to non-limited circuits (9.4) meets:		—
	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:		—
	Metal (except magnesium); or		N/A
	Non-metallic materials have flammability classification V-1 or better		P
	3) ENCLOSURE and any baffle or flame barrier have adequate rigidity		P
9.4	**Limited-energy circuit**		N/A
	a) Potential not more than 30 r.m.s. and 42,4 V peak, or 60 V d.c.	No limited-energy circuit	N/A
	b) Current limited by one of following means:		—
	1) Inherently or by impedance (see Table 17); or		N/A
	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**		N/A
	Flammable liquids contained in or specified for use with equipment do not cause spread of fire	No flammable liquids	N/A
	RISK is reduced to a tolerable level:		—
	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**		P
9.6.1	General		P
	MAINS supplied equipment protected		P

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	BASIC INSULATION between MAINS parts of opposite polarity provided	(see Form A.14 and A.15)	P
	Overcurrent protection devices not fitted in the protective conductor		P
	Fuses or single-pole circuit-breakers not fitted in neutral (multi-phase equipment)		N/A
9.6.2	PERMANENTLY CONNECTED EQUIPMENT		N/A
	Overcurrent protection device:		—
	Fitted within the equipment; or		N/A
	Specified in manufacturer's instructions		N/A
9.6.3	Other equipment		P
	Protection within the equipment	Protection device provided within the equipment	P
10	**EQUIPMENT TEMPERATURE LIMITS AND RESISTANCE TO HEAT**		—
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)	—
	– at an specified ambient temperature of 40 °C	The equipment tested maximum ambient temperature at 40 ℃	P
	– for equipment rated above 40 °C ambient temperature limits not exceeded raised by the difference to 40 °C		N/A
	Heated surfaces necessary for functional reasons exceeding specified values:		—
	– 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**		P
	Limits not exceeded in:	(see Form A.26A)	—
	NORMAL CONDITION		P
	SINGLE FAULT CONDITION		P
10.3	**Other temperature measurements**		P
	Following measurements conducted if applicable:	(see Form A.26A)	—
	a) Value of 60 °C of field-wiring terminal box not exceeded	No field-wiring terminal box	N/A
	b) Surface of flammable liquids and parts in contact with this liquids	No flammable liquids	N/A
	c) Surface of non-metallic ENCLOSURES		P

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	d) Parts made of insulating material supporting parts connected to MAINS supply		P
	e) Terminals carrying a current more than 0,5 A		P
10.4	**Conduct of temperature tests**		P
10.4.1	General		P
	Tests conducted under reference test conditions and manufacturer's instructions	(see Form A.26A)	P
	Tests alternatively conducted at the least favourable ambient temperature within the RATED ambient temperature .....:	(See above)	—
10.4.2	Temperature measurement of heating equipment	(see Form A.26A)	P
	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**		P
10.5.1	Integrity of CLEARANCE and CREEPAGE DISTANCES		N/A
10.5.2	Non-metallic ENCLOSURES		P
	Within 10 min after treatment:		—
	Equipment subjected to suitable stresses of 8.2 and 8.3 complying with criteria of 8.1	(see Form A.27)	P
10.5.3	Insulating material		P
	a) Parts supporting parts connected to MAINS supply		P
	b) TERMINALS carrying a current more than 0,5 A		P
	Examination of material data; or		N/A
	in case of doubt:		P
	1) Ball pressure test; or	(see Form A.28)	P
	2) Vicat softening test of ISO 306		N/A
11	**PROTECTION AGAINST HAZARDS FROM FLUIDS AND SOLID FOREIGN OBJECTS**		—
11.1	**General**		P
	Protection to OPERATORS and surrounding area provided by EQUIPMENT		P
	All fluids specified by manufacturer considered		P
11.2	**Cleaning**	(see Form A.30)	P
11.3	**Spillage**		N/A
11.4	**Overflow**		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
11.5	**Battery electrolyte**	No such battery (Only Back-up coin battery) See clause 13.2.2	N/A
	Battery electrolyte leakage presents no HAZARD		N/A
11.6	**Equipment RATED with a degree of ingress protection (IP code)**		N/A
11.6.1	General		N/A
	Equipment marked with IP code ..... :	IPX0	—
	Conditions specified in the documentation		N/A
11.6.2	Conditions for testing		N/A
	Equipment in clean and new condition, all parts in place and mounted as specified by manufacturer		N/A
	Complete equipment tested, or		N/A
	representative parts tested		N/A
	HAND-HELD EQUIPMENT and PORTABLE EQUIPMENT placed in least favourable position of NORMAL use		N/A
	Other equipment positioned or installed as specified		N/A
	TERMINALS provided with protective cap or cover, are installed as specified by manufacturer		N/A
	The equipment is operating (energized) during the treatment except:		—
	a) If manufacturer specifies degrees of protection for non-operating (de-energized) equipment, or		N/A
	b) Equipment is operating or non-operating during the treatment with does not affect the test results		N/A
11.6.3	Protection against solid foreign objects (including dust)		N/A
	Applicable test of IEC 60529 for protection against solid foreign objects conducted	IPX0	N/A
	Additionally inspection of equipment resulted:		—
	a) No deposit on insulation parts that could lead to a HAZARD		N/A
	b) No created accumulations that have the potential to cause spread of fire		N/A
11.6.4	Protection against water		N/A
	Applicable test of IEC 60529 for protection against water conducted	IPX0	N/A
	If any water has entered, safety is not impaired, inspection of equipment resulted:		—
	a) No deposit on insulation parts that could lead to a HAZARD		N/A
	b) Water has not reached hazardous live parts or windings which are not designed to operate when wet		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) No accumulations near the end of cable nor enter the cable where it could cause a HAZARD		N/A
	d) No accumulations where it could lead to a HAZARD taking in consideration movement of the equipment		N/A
11.7	**Fluid pressure and leakage**		N/A
11.7.1	Maximum pressure ..... :		—
	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 checked by inspection or if a HAZARD could arise subjected to hydraulic test, if:		—
	a) product of pressure and volume > 200 kPa·l; and		N/A
	b) pressure > 50 kPa		N/A
	Safety evidence established by calculation in acc. to national authorities (e.g. Pressure Equipment Directive 2014/68/EU)		N/A
	Parts of refrigerating systems meets pressure-related requirements of EN 378-2 or IEC 60335-2-89 as applicable		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**		—
12.1	**General**		N/A
	Equipment provides protection		N/A
12.2	**Equipment producing ionizing radiation**	No ionizing radiation.	N/A
12.2.1	Ionizing radiation		N/A
12.2.1.1	General		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Equipment meets the following requirements:		—
	a) if intended to emit radiation meets requirements of 12.2.1.2; or		N/A
	tested, classified and marked in accordance to IEC 62598		N/A
	b) if only emits stray radiation meets requirements of 12.2.1.3		N/A
12.2.1.2	Equipment intended to emit radiation		—
	Effective dose rate of radiation measured.....:	No such parts	—
	If dose rate exceeds 5 µSv/h marked with the following:		—
	a) symbol 17 (ISO 361)		N/A
	b) abbreviations of the radionuclides.....:		—
	c) with maximum dose at 1 m; or .....:		—
	with dose rate value between 1 µSv/h and 5 µSv/h in m.....:	No such parts	—
12.2.1.3	Equipment not intended to emit radiation		—
	Limit for unintended stray radiation of 1 µSv/h at any easily reached point kept .....:	No such parts	N/A
12.2.2	Accelerated electrons		N/A
	Compartments opened only by the use of a TOOL	No Ultraviolet radiation	N/A
***12.3**	**Optical radiation**		N/A
	No unintentional HAZARDOUS escape of optical radiation as ultraviolet, visible or infrared radiation, including light emitting diodes:		—
	– Checked by inspection; and		N/A
	– Radiation sources assessed in acc. to the requirements of IEC 62471, except for sources considered to be safe (Table 22) or conditionally safe (Table 23).		N/A
	– Lamp and lamp systems assessed to Risk Groups 1, 2, or 3 of IEC 62471 are labelled in acc. to IEC 62471-2		N/A
	– If labelling impractical, lamp or lamp systems marked with symbol 14		N/A
	– Protective measures, restrictions on use, and operating instructions that may be necessary are provided, including the applicable conditions of use of Table 23.		N/A
12.4	**Microwave radiation**		N/A
	Power density does not exceed 10 W/m^2.....:	No microwave radiation	N/A
12.5	**Sonic and ultrasonic pressure**	No sonic and ultrasonic pressure	N/A
12.5.1	Sound level		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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	No 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:		—
	Marked with Symbol 14 of Table 1		N/A
	and following information in the documentation:		—
	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
***12.6**	**Laser sources**	No laser sources	N/A
	Equipment meets requirements of IEC 60825-1		N/A
13	**PROTECTION AGAINST LIBERATED GASES AND SUBSTANCES, EXPLOSION AND IMPLOSION**		—
13.1	**Poisonous and injurious gases and substances**	No such gases inside	N/A
	No hazardous substances liberated in NORMAL CONDITION and in SINGLE FAULT CONDITION		N/A
	If potentially-hazardous substances are liberated:		—
	Operator is not directly exposed to a quantity of the substance that could cause harm		N/A
	Requirements to discharge of hazardous substances during NORMAL operation in accordance to manufacturer's instructions not considered as liberation	No such component	N/A
	Attached data/test reports demonstrate conformity		N/A
13.2	**Explosion and implosion**		P
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

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Cannot be obstructed		N/A
13.2.2	Batteries and battery charging		P
	If explosion or fire HAZARD could occur:	Approved coin battery used	—
	Protection incorporated in the equipment; or		P
	Instructions specify batteries with built-in protection		N/A
	In case of wrong type of battery used:		—
	No HAZARD; or		P
	Warning by marking and within instructions		N/A
	Equipment with means to charge rechargeable batteries:		—
	Warning against the charging of non-rechargeable batteries; and	Only back-up coin battery used on the LCD panel board	N/A
	Type of rechargeable battery indicated; or		N/A
	Symbol 14 used		N/A
	Battery compartment design		N/A
	Single component failure	(see TABLE A.37)	P
	Polarity reversal test		N/A
*13.2.3	Implosion of cathode ray tubes	No 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**		—
14.1	**General**		P
	Where safety is involved, components and subassemblies meet relevant requirements	(see TABLE 1.A)	P
14.2	**Motors**		N/A
14.2.1	Motor temperatures	Approval motor used	N/A
	Does not present a HAZARD when stopped or prevented from starting; or		N/A
	Protected by over-temperature or thermal protection device conform with 14.3		N/A
14.2.2	Series excitation motors		N/A
	Connected direct to device, if overspeeding causes a HAZARD		N/A
14.3	**Overtemperature protection devices**	(see TABLE 1.A)	P

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Devices operating in a SINGLE FAULT CONDITION		P
	a) Reliable function is ensured		P
	b) RATED to interrupt maximum current and voltage		P
	c) Does not operate in NORMAL USE		P
	If self-resetting device used to prevent a HAZARD, protected part requires intervention before restarting		P
14.4	**Fuse holders**		P
	No access to HAZARDOUS LIVE parts		P
14.5	**MAINS voltage selecting devices**		N/A
	Accidental change not possible		N/A
14.6	**MAINS transformers tested outside equipment**		P
14.7	**Printed wiring boards**		P
	Data shows conformity with V-1 of IEC 60695-11-10 or better; or	(see TABLE 1.A)	P
	Test shows conformity with V-1 of IEC 60695-11-10 or better		N/A
	Not applicable for printed wiring boards with limited-energy circuits (9.4)		N/A
14.8	**Circuits used to limit TRANSIENT OVERVOLTAGES**		N/A
	Test conducted between each pair of MAINS SUPPLY TERMINALS		N/A
	No ignition or overheating of other materials :		—
	– no ignition		N/A
	– no heat to other parts above the self-ignition points		N/A
	Safely suppressing and properly functional after applied tests		N/A
15	**PROTECTION BY INTERLOCKS**		—
15.1	**General**		P
	Interlocks are designed to remove a HAZARD before OPERATOR exposed		P
15.2	**Prevention of reactivation**	Program reset by operator	P
15.3	**Reliability**		P
	Single fault unlikely to occur; or	The door does not opened by vacuum, No hazard	P
	Cannot cause a HAZARD	Test by 10 000 cycle of operation	P
16	**HAZARDS RESULTING FROM APPLICATION**		—
16.1	**REASONABLY FORESEEABLE MISUSE**		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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:		—
	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**		—
	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:		—
	a) RISK analysis		N/A
	Identifies HAZARDS and estimates RISK		N/A
	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:		—
	Information contained how to mitigate these RISKS		N/A
	Following principles in methods of RISK reduction applied by manufacturer in given order:		—
	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

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

ANNEX F	**ROUTINE TESTS**		—
	Manufacturer ´s declaration		P

ANNEX H	**QUALIFICATION OF CONFORMAL COATINGS FOR PROTECTION AGAINST POLLUTION**		—
H.1	**General**		N/A
	Conformal coatings meet the requirements of Clause H.2 and H.3.		N/A
H.2	**Technical properties**		N/A
	Technical properties of conformal coatings are suitable for the intended application. In particular:		—
	a) Manufacturer indicate that it is a coating for PWBs;		N/A
	b) RATED operating temperature include the temperature range of the indicated application;		N/A
	c) CTI, insulation resistance and dielectric strength are suitable for the intended application;		N/A
	d) Coating have adequate UV resistance, if it is exposed to sunlight;		N/A
	e) Flammability RATING of the coating is at least the required flammability RATING of the applied PWB.		N/A
H.3	**Qualification of coatings**		N/A
	Coating complies with the conformity requirements.		N/A

ANNEX K	**INSULATION REQUIREMENTS NOT COVERED BY CLAUSE 6.7**		—
			N/A

IEC 61010-1			
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
4.4.2.3	1	Protective conductor open	1:16:00	No adverse effects, No hazard, No damage, Not exceed the temperature limited (Refer to appended form A.26A)	P
4.4.2.8	2	Output short	1:06:00	LCD panel not operating, No hazard, No damage, Not exceed the temperature limited (Refer to appended form A.26A)	P
4.4.2.10	3	Ventilation block	1:36:00	No adverse effects, No hazard, No damage, Not exceed the temperature limited (Refer to appended form A.26A)	P
4.4.2.10	4	Main unit Fan lock	1:52:00	No adverse effects, No hazard, No damage, Not exceed the temperature limited (Refer to appended form A.26A)	P
4.4.2.10	5	Pump module Fan lock	1:44:00	No adverse effects, No hazard, No damage, Not exceed the temperature limited (Refer to appended form A.26A)	P
4.4.2.10	6	Pump module AC Fan lock	3:28:00	No adverse effects, No hazard, No damage, Not exceed the temperature limited (Refer to appended form A.26A)	P
4.4.2.11	7	Heater Bi-metal open	1:20:00	No adverse effects, No hazard, No damage, Not exceed the temperature limited (Refer to appended form A.26A)	P
4.4.2.11	8	Heater Bi-metal Short	1:43:00	No adverse effects, No hazard, No damage, Not exceed the temperature limited (Refer to appended form A.26A)	P
4.4.2.13	9	Interlock	00:00:01	Error Message and alarmed (Door not closed)	P

NOTE Td = Test duration in hh:mm:ss
Record dielectric strength test on Form A.18 and temperature tests on Forms A.26A and / or A.26B.
Record in the comments column for each test whether carried out during or after SINGLE FAULT CONDITION.

Supplementary information:

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

5.1.3c)	**TABLE: MAINS supply**		**Form A.2**	P
	Marked rating ..... :	220-240	V	—
	Phase ..... :	1 Phase		—
	Frequency ..... :	50/60	Hz	—
	Current ..... :	-	A	—
	Power ..... :	-	W	—
	Power ..... :	1.5	kVA	—

Test No.	Voltage [V]	Frequency [Hz]	Current [A]	Power [W]	Power [VA]	Comments
1	198	50	4.01	770.9	793.9	
2	220	50	3.59	746.5	783.0	
3	240	50	3.74	860.5	897.9	
4	264	50	4.02	975.5	1 051.0	
5	198	60	4.59	907.7	909.9	
6	220	60	4.60	1 007.7	1 014.1	
7	240	60	5.09	1 217.6	1 220.8	
8	264	60	5.15	1 350.1	1 302.1	

NOTE – Measurements are only required for marked ratings. Initial inrush currents are not regarded.

Supplementary information:
Operating condition: Sterilize mode, continuous operating

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

5.3	**TABLE: Durability of markings**	**Form A.3**	P

Marking method (see NOTE)	Agent
1) Adhesive label	~~A Water~~
2) Ink printed	B Isopropyl alcohol 70%
~~3) Laser marked~~	~~C (specify agent)~~
~~4) Film coated (plastic foil control panel)~~	~~D (specify agent)~~
~~5) Imprinted on plastic (moulded in)~~	~~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)	1)
MAINS supply (5.1.3)	1)
Fuses (5.1.4)	-
Terminals and operating devices (5.1.5.2)	-
Switches and circuit breakers (5.1.6)	2)
Double/reinforced equipment (5.1.7)	-
Field wiring Terminal boxes (5.1.8)	-
Warning marking (5.2)	1)
Battery charging (13.2.2)	-

Method	Test agent	Remains legible	Label loose	Curled edges	Comments
		Verdict	Verdict	Verdict	
1)	B	Yes	No	No	Rubbed for 30 s
2)	B	Yes	N/A	N/A	Rubbed for 30 s

Supplementary information:

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

6.2	**TABLE: List of ACCESSIBLE parts**	**Form A.4**	P
~~6.1.2~~	~~Exceptions~~		—
6.2	Determination of ACCESSIBLE parts		—

Item	Description	Determination method (NOTE 5)	Exception under 6.1.2 (NOTE 4)
1	LCD panel	V, J, R	N/A
2	Plastic enclosure	V, J, R	N/A
3	Pump module plastic enclosure	V, J, R	N/A

NOTE 1 – Test fingers and pins are to be applied without force unless a force is specified (see 6.2.2)
NOTE 2 – Special consideration should be given to inadequate insulation and high voltage parts (see 6.2)
NOTE 3 – Parts are considered to be ACCESSIBLE if they could be touched in the absence of any covering which is not considered to provide suitable insulation (see 6.4).
NOTE 4 – Capacitance test may be required (see Form A.5).
NOTE 5 – The determination methods are:
V = visual; R = rigid test finger; J = jointed test finger; P3 = pin 3 mm diameter; P4 = pin 4 mm diameter.

Supplementary information:

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

6	**TABLE: Values in NORMAL CONDITION**	**Form A.5**	
~~6.1.2~~	~~Exceptions~~	11.2 Cleaning and decontamination	—
6.3.1	Values in NORMAL CONDITION (see NOTE 1)	~~11.3 Spillage~~	—
~~6.6.2~~	~~Terminals for external circuit~~	~~11.4 Overflow~~	—
6.10.3	Plugs and connections		—

Item (see Form A.4)	Voltage			Current				Capacitance		5 s test (NOTE)			Comments
	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	
1	1.35	-	-	-	-	-	-	-	-	-	-	-	
2	1.10	-	-	-	-	-	-	-	-	-	-	-	
3	2.00	-	-	-	-	-	-	-	-	-	-	-	
Sub-Clause 6.10.3	-	-	-	-	-	-	-	-	-	16	14.56	-	
1	1.36	-	-	-	-	-	-	-	-	-	-	-	
2	1.09	-	-	-	-	-	-	-	-	-	-	-	(Sub-Clause 11.2)
3	1.98												

NOTE – A 10 s test is specified in 6.1.2 a) b). A. 5 s test is specified in 6.10.3. The capacitance level versus voltage below the limits given from figure 3 of IEC 61010-1.

Supplementary information:

Voltage Measured

Switch On: L-N: 16 V, L-G: 54 V, N-G: 20 V, Switch Off: L-N: 14 V, L-G: 28 V, N-G: 6 V

Capacitor Measured

Switch on: L-N: 910.19 nF, L-G: 38.52 nF, N-G: 38.73 nF, Switch off: L-N: 16.00 pF, L-G: 7.63 pF, N-G: 7.59 pF

Q=CV

Switch On: L-N: 14.56 uC, L-G: 2.08 uC, N-G: 0.78 uC, Switch Off: L-N: 0.01 uC, L-G: 0.01 uC, N-G 0.01 uC

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

6.3.2	**TABLE: Values in SINGLE FAULT CONDITION**										**Form A.6**	P
Item	Subclause and	Voltage			Transient (see NOTE)		Current				Capacitance	Comments
(see Form A.4)	fault No. (see Form A.1)	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 (see NOTE)	
1	1	3.49	-	-	-	-	-	-	-	-	-	
2		7.19	-	-	-	-	-	-	-	-	-	
3		2.67	-	-	-	-	-	-	-	-	-	
1	2	10.24	-	-	-	-	-	-	-	-	-	
2		7.81	-	-	-	-	-	-	-	-	-	
3		9.10	-	-	-	-	-	-	-	-	-	
1	3	1.27	-	-	-	-	-	-	-	-	-	
2		0.83	-	-	-	-	-	-	-	-	-	
3		2.13	-	-	-	-	-	-	-	-	-	
1	4	1.25	-	-	-	-	-	-	-	-	-	
2		0.86	-	-	-	-	-	-	-	-	-	
3		1.85	-	-	-	-	-	-	-	-	-	
1	5	1.29	-	-	-	-	-	-	-	-	-	
2		0.88	-	-	-	-	-	-	-	-	-	
3		1.83	-	-	-	-	-	-	-	-	-	
1	6	1.29	-	-	-	-	-	-	-	-	-	
2		0.88	-	-	-	-	-	-	-	-	-	
3		1.87	-	-	-	-	-	-	-	-	-	

6.3.2	TABLE: Values in SINGLE FAULT CONDITION										Form A.6	P
Item (see Form A.4)	Subclause and fault No. (see Form A.1)	Voltage			Transient (see NOTE)		Current				Capacitance	Comments
		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 (see NOTE)	
1	7	1.26	-	-	-	-	-	-	-	-	-	
2		0.88	-	-	-	-	-	-	-	-	-	
3		1.80	-	-	-	-	-	-	-	-	-	
1	8	1.29	-	-	-	-	-	-	-	-	-	
2		0.84	-	-	-	-	-	-	-	-	-	
3		1.85	-	-	-	-	-	-	-	-	-	
1	9	1.30	-	-	-	-	-	-	-	-	-	
2		0.89	-	-	-	-	-	-	-	-	-	
3		1.86	-	-	-	-	-	-	-	-	-	
NOTE – Transient voltages must be below the limits given from Figure 2 and the capacitance below the limits from figure 3 of IEC 61010-1.												
Supplementary information:												

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

6.5.2.2	**TABLE: Cross-sectional area of bonding conductors**	**Form A.7**	P
Conductor location	CROSS-SECTIONAL AREA [mm²]		Verdict
Metal enclosure	0.75		P

Supplementary information:

6.5.2.3	**TABLE: Tightening torque test**	**Form A.8**	P
Conductor location	Size of screw	Tightening torque [Nm]	Verdict
Internal metal enclosure	4.0 mm	1.2	P

Supplementary information:

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

6.5.2.4	**TABLE: BONDING impedance of plug-connected equipment** **Form A.9**			P
ACCESSIBLE part under test	Test current [A]	Voltage attained after 1 min [V]	Calculated resistance (Maximum 0,1 ~~or 0,2 Ω~~) [Ω] (NOTE 1)	Verdict
Inlet to Pump module earth parts	25	2.66	0.093	P
NOTE 1 – For none-detachable power cord the impedance between protective conductor plug pin of MAINS cord and each ACCESSIBLE part shall not exceed 0,2 Ohm.				
Supplementary information:				

6.5.2.5	**TABLE: BONDING impedance of PERMANENTLY CONNECTED EQUIPMENT** **Form A.10**			N/A
ACCESSIBLE part under test	Test current [A]	Voltage attained after 1 min (maximum 10 V) [V]		Verdict
Supplementary information:				

6.5.2.6	**TABLE: Transformer PROTECIVE BONDING screen** **Form A.11**			N/A
ACCESSIBLE part under test	Test current (see NOTE) [A]	Voltage attained after 1 min (maximum 10 V) [V]	Calculated resistance (maximum 0,1 Ω) [Ω]	Verdict
NOTE – Test current must be twice the value of the overcurrent protection means of the winding. Test is specified in 6.5.2.6 a) or b).				
Supplementary information:				

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

6.5.4	**TABLE: PROTECTIVE IMPEDANCE**	**Form A.12**	N/A

A single component

Component	Location	Measured		Calculated	Rated		Verdict	Comments
		Working voltage [V]	Current [A]	Power dissipation [W]	Working voltage [V]	Power dissipation [W]		

A combination of components

Component	Location	Comments

NOTE – A PROTECTIVE IMPEDANCE shall not be a single electronic device that employs electron conduction in a vacuum, gas or semiconductor.

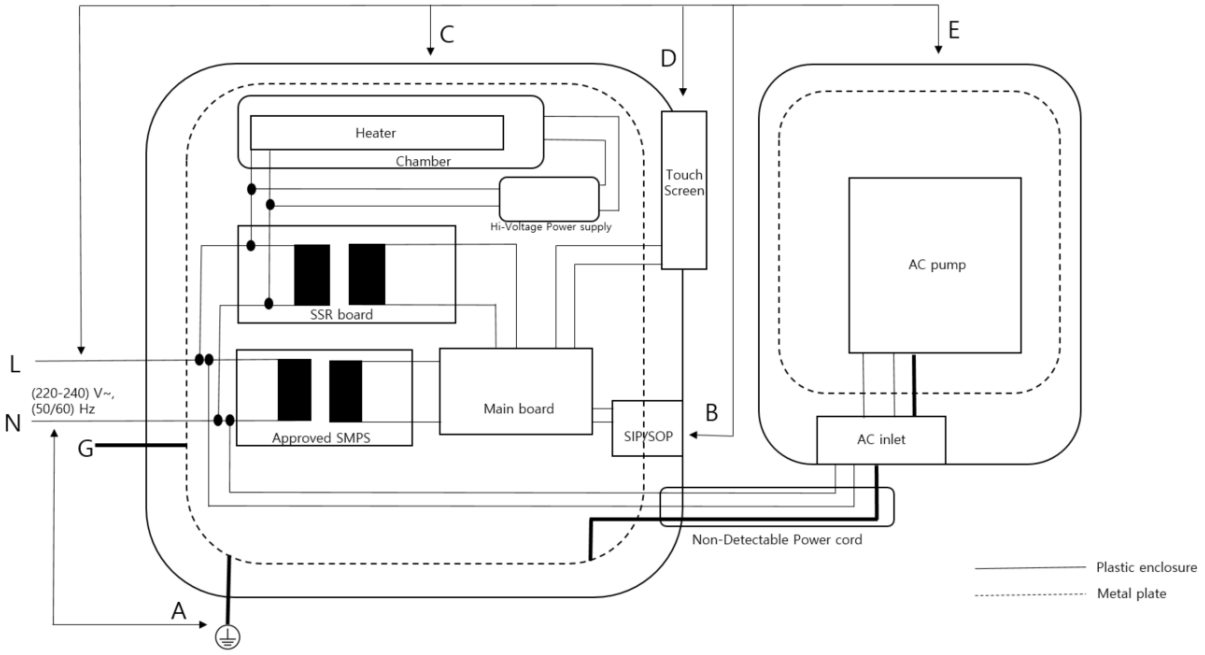
Supplementary information:

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

6.5.6	**TABLE: Current- or voltage-limiting device**						**Form A.13**	N/A
Component	Location	Measured		Rated		Verdict	Comments	
		Working voltage [V]	Current [A]	Working voltage [V]	Current [A]			
Supplementary information:								

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

6.7	**TABLE: Insulation requirements - Block diagram of system -**	**Form A.14**	P



Pollution degree .....: 2	Overvoltage category .....: II

Area	Location	Insulation type (NOTE 1)	WORKING VOLTAGE			CLEARANCE (NOTE 3)	CREEPAGE DISTANCE (NOTE 3)				Test voltage (NOTE 2)	Comments (NOTE 3)
			RMS [V]	Peak [V]	Freq. [kHz]	[mm]	PWB [mm]	CTI	Other [mm]	CTI	[V]	
A	Primary to Protective earth	BI	240	-	-	4.1	-	-	5.4	IIIb	1 500	No breakdown
B	Primary to SIP/SOP	DI/RI	240	-	-	10.0	-	-	10.0	IIIb	3 000	No breakdown
C	Primary to Main unit enclosure	DI/RI	240	-	-	10.0	-	-	10.0	IIIb	3 000	No breakdown
D	Primary to LCD panel	DI/RI	240	-	-	6.0	-	-	8.0	IIIb	3 000	No breakdown
E	Primary to Pump module enclosure	DI/RI	240	-	-	6.0	-	-	8.0	IIIb	3 000	No breakdown

NOTE 1 – Type of insulation:
BI = BASIC INSULATION
DI = DOUBLE INSULATION
PI = PROTECTIVE IMPEDANCE
RI = Reinforced INSULATION
SI = Supplementary INSULATION
see also Form A.15 for further details

NOTE 2 - Types of voltage
Peak impulse test voltage (pulse)
r.m.s.
d.c.
peak

NOTE 3 - OVERVOLTAGE CATEGORIES or POLLUTION DEGREES which differ should be shown under "Comments"

Supplementary Information:
Cut-off current: 40 mA

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

6.7	**TABLE: Insulation requirements - CLEARANCES and CREEPAGES**		**Form A.15**	P
~~6.2.2~~	~~Examination~~	~~6.5.4~~	~~Protective impedance~~	—
6.4.2	ENCLOSURES and protective barriers	~~6.5.6~~	~~Current- or voltage-limiting device~~	—
6.4.4	~~Impedance~~	9.6.1	BASIC INSULATION between opposite polarity	—

Area	Location (See Form A.14)	Insulation type (NOTE 1)	WORKING VOLTAGE (NOTE 2)			CLEARANCE		CREEPAGE DISTANCE		CTI	Verdict	Comments
			RMS [V]	Peak [V]	Frequency [kHz]	Required [mm]	Measured [mm]	Required [mm]	Measured [mm]			
A	Primary to Protective earth	BI	240	-	-	1.5	4.1	3.0	5.4	IIIb	P	
B	Primary to SIP/SOP	RI	240	-	-	3.0	10.0	6.0	10.0	IIIb	P	
C	Primary to Main unit enclosure	RI	240	-	-	3.0	10.0	6.0	10.0	IIIb	P	
D	Primary to LCD panel	RI	240	-	-	3.0	6.0	6.0	8.0	IIIb	P	
E	Primary to Pump module enclosure	RI	240	-	-	3.0	6.0	6.0	8.0	IIIb	P	

NOTE 1 – refer to Form A.14 for type of insulation shown in the insulation diagram NOTE 2 – to be used for definition of required insulation (see Form A.14)

Input supply voltage…….:	240	V	60	Hz

Supplementary information:

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

6.7	**TABLE: Insulation requirements – CLEARANCES and CREEPAGES**		**Form A.16**	P
6.4.2	ENCLOSURES or PROTECTIVE BARRIERS	9.6.1	Overcurrent protection basic insulation between MAINS parts	—
8	Mechanical resistance to shock and impact	10.5.1	Integrity of CLEARANCES and CREEPAGE DISTANCES	—

Area	Location (See Form A.14)	Insulation type	Mechanical tests (NOTE)					Test at max.	Measured after test (if required)		Verdict	Comments
			Applied force	Rigidity (8.2)		Drop (8.3)		RATED ambient	CLEARANCE	CREEPAGE DISTANCE		
			[N]	Static (8.2.1)	Impact (8.2.2)	Normal (8.3.1)	Hand-held/ Plug-in	(10.5.1)	[mm]	[mm]		
A	Primary to Protective earth	BI	30	P	P	P	-	40 ℃	4.1 (1.5)	5.4 (3.0)	P	
B	Primary to SIP/SOP	RI	30	P	P	P	-	40 ℃	10.0 (3.0)	10.0 (6.0)	P	
C	Primary to Main unit enclosure	RI	30	P	P	P	-	40 ℃	10.0 (3.0)	10.0 (6.0)	P	
D	Primary to LCD panel	RI	30	P	P	P	-	40 ℃	6.0 (3.0)	8.0 (6.0)	P	
E	Primary to Pump module enclosure	RI	30	P	P	P	-	40 ℃	6.0 (3.0)	8.0 (6.0)	P	

NOTE – Refer to Form A.18 for dielectric strength tests following the above tests.

Supplementary information:
-( ): Required distance

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

6.7.2.2.2	**TABLE: Reliability of potted components**	**Form A.17 (optional)**	N/A
14.1 b)	**Components and subassemblies**		

Temperature Cycling Test	
Manufacturer ..... :	
Type ..... :	
Construction ..... :	
Potting compound ..... :	
CREEPAGE DISTANCES measured ..... :	
CLEARANCES measured ..... :	
Thickness through insulation..... :	
Adhesive test Pass/Fail..... :	
Test temperature T °C..... :	

Cycles at U= AC 500 V				Leakage current (at AC 500 V) mA			
Number of cycles	Date			68 h / 125 °C	1 h / 25 °C	2 h / 0 °C	1 h / 25 °C
1. Cycle from		to					
2. Cycle from		to					
3. Cycle from		to					
4. Cycle from		to					
5. Cycle from		to					
6. Cycle from		to					
7. Cycle from		to					
8. Cycle from		to					
9. Cycle from		to					
10. Cycle from		to					

After Cycling Test :		
Humidity conditioning	48 h	
Requirements for dielectric strength (s. insulation diagram)	Test voltage V r.m.s.	Verdict
Basic insulation _____ V r.m.s.		
Supplementary insulation _____ V r.m.s.		
Reinforced insulation _____ V r.m.s.		
NOTE - to be used for evaluation of components containing insulation through solid insulation, when the component standard require thermal cycling test. Ref Clause 14.1 and Figure 15, option b)		
Supplementary information:		

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

6.8	**TABLE: Dielectric strength tests**	**Form A.18**	P
4.4.4.1 b)	Conformity after application of SINGLE FAULT CONDITIONS[1]		P
6.4	Primary means of protection[2]		P
6.6	Connections to external circuits		P
6.7	Insulation requirements[2] (see Annex K)		P
6.10.2	Fitting of non-detachable MAINS supply cords[1]		P
9.2 a) 2)	Eliminating or reducing the sources of ignition within the equipment		N/A
9.4 c)	Limited-energy circuit		N/A
9.6.1	Overcurrent protection basic insulation between MAINS - parts		P
	Test site altitude .....:	2 000 m	—
	Test voltage correction factor (see table 10) .....:	1.0	—

Location or references from Forms A.1 and A.14	Clause or sub-clause	Humidity	Working voltage	Test voltage	Comments (NOTE)	Verdict
		Yes/No	[r.m.s./d.c.]	[r.m.s./peak/d.c.]		
1 to 9 (Form A.1)	4.4.4.1 b)	Yes	240	1 500	No breakdown	P
A (Form A.14)	6.8	Yes	240	1 500	No breakdown	P
B (Form A.14)	6.8	Yes	240	3 000	No breakdown	P
C (Form A.14)	6.8	Yes	240	3 000	No breakdown	P
D (Form A.14)	6.8	Yes	240	3 000	No breakdown	P
E (Form A.14)	6.8	Yes	240	3 000	No breakdown	P

[1] Record the fault, test or treatment applied before the dielectric strength test. [2] Humidity preconditioning required.
NOTE: Test duration may be recorded.

Supplementary information:
Cut-off current: 40 mA

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

6.10.2	**TABLE: Cord anchorage**					**Form A.19**	P
Location		Mass [kg]	Pull [N]	Verdict	Torque [Nm]	Verdict	Comment
Main unit to Pump module		21	100	P	0.35	P	Not exceed 2 mm (Measured 1.76 mm)
Dielectric strength test for 1 min. (6.8.3.1)..... :			3 000		V r.m.s.		P

Supplementary information:
Cut-off current: 40 mA

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

7.	**TABLE: Protection against mechanical HAZARDS** **Form A.20**	N/A
7.3.4	Limitation of force and pressure	—
7.3.5	Gap limitations between moving parts	—

Part / Location	Clause 7.3.4		Clause 7.3.5.1								Clause 7.3.5.2			Verdict	Comments
	Continuous	Temporary	Minimum gaps [mm]								Maximum gaps [mm]				
	Contact pressure max. 50 N /cm² @ max. 150 N	max. 250 N / 3 cm² @ max. 0,75 s	Torso 500	Head 300	Leg 180	Foot 120	Toes 50	Arm 120	Hand 100	Finger 25	Head 120	Foot 35	Finger 4		

Supplementary information:

IEC 61010-1			
Clause	Requirement – Test	Result - Remark	Verdict
7.4	**TABLE: Stability**	**Form A.20A**	P
	Equipment height / mass ..... :	330 mm 41 kg	—
	Equipment (Containers) loaded ..... :	No	—
	Castors at unfavourable position ..... :	No	—
	Doors, drawers and movable arms closed ..... :	No	—
	Doors and drawers at unfavourable position ..... :	No	—

Location	Tilt angle	Applied force				Comments	Verdict
	10°	250 N	20% [N]	800 N	4 times load [N]		
Front side	P	—	—	—			P
Left side	P	—	—	—			P
Rear side	P	—	—	—			P
Right side	P	—	—	—			P
Top side	—	—	—	—			N/A
Working surface	—	—	—	—			N/A
Ledge	—	—	—	—			N/A
Castor / support foot					—		N/A
Castor / support foot removed							N/A

Supplementary information:
Equipment mass = Main unit with Pump module (total 41 kg)

7.6	**TABLE: Wall mounting**	**Form A.20B**	N/A
	Equipment weight ..... :	kg	—
	Equipment mounted as specified by manufacturer .. :	[yes / no]	—
	Equipment mounted at plasterboard (drywall) ..... :	[yes / no]	—
	More than one fastener used ..... :	[yes / no]	—
	Test maintained (after 5 s to 10 s to full load) ..... :	1 min	—

Location	Applied weight		Comments	Verdict
	4 times weight [kg]	2 times weight [kg]		
Mounting brackets				

Supplementary information:

IEC 61010-1							
Clause	Requirement – Test	Result - Remark					Verdict
8.2	**TABLE: ENCLOSURE rigidity test**					**Form A.21A**	P
8.2.1	Static test						P
	Material of enclosure .....:	Non-metallic					—
	Preparation for the test:	After Cl. 10.5.2					—
	Operated at ambient temperature .....:	40	°C		h		—
Location		Comments					Verdict
1) Top of enclosure (Plastic)		No damage, No hazard					P
2) Left of enclosure (Plastic)		No damage, No hazard					P
3) Right of enclosure (Plastic)		No damage, No hazard					P
4) Front of enclosure (Plastic)		No damage, No hazard					P
5) Rear of enclosure (Plastic)		No damage, No hazard					P
Supplementary information:							

8.2.2	**TABLE: Impact test**			P
	Material of enclosure .....:	Non-metallic		—
	Corresponding IK-code.....:	IK08		—
	Preparation for the test:	After Cl. 10.5.2		—
	Cooled to (temperature) .....:	-	°C	—
Location		Comments		Verdict
1) Top of enclosure (Plastic)		No damage, No hazard		P
2) Left of enclosure (Plastic)		No damage, No hazard		P
3) Right of enclosure (Plastic)		No damage, No hazard		P
4) Front of enclosure (Plastic)		No damage, No hazard		P
5) Rear of enclosure (Plastic)		No damage, No hazard		P
6) Bottom of enclosure (Plastic)		No damage, No hazard		P
Supplementary information:				

IEC 61010-1				
Clause	Requirement – Test		Result - Remark	Verdict
8.3	**TABLE: Drop test**		**Form A.21B**	P
8.3.1	Other equipment			P
Location	Raised up to		Comments	—
	[mm]	30 °		
1) Left side of Main unit	25	-	No damage, No hazard	P
2) Right side of Main unit	25	-	No damage, No hazard	P
3) Front side of Main unit	25	-	No damage, No hazard	P
4) Rear side of Main unit	25	-	No damage, No hazard	P
Supplementary information:				
8.3.2	HAND-HELD EQUIPMENT and DIRECT PLUG-IN EQUIPMENT			N/A
	Material of enclosure .....:		Metal / non-metallic	—
	Preparation for the test:			—
	Cooled to (temperature) .....:		°C	—
Location			Comments	Verdict
1) Side				
2) Edge				
3) Corner				
Supplementary information:				

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 (9.1 a, b or c)	Protection details	Verdict
1	Circuit, Component	9.1(a)	Complied with clause 4.4	P
2	External enclosure (Plastic)	9.1(c)	Complied with clause 9.3	P
Supplementary information:				

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

9.3.2	**TABLE: Constructional requirements**	**Form A.23**	N/A
14.7	Printed wiring boards		N/A

Material tested ..... :		—
Generic name ..... :		—
Material manufacturer..... :		—
Type..... :		—
Colour ..... :		—
Conditioning details ..... :		—

		Sample					
		1	2	3	4	5	6
Thickness of specimen	mm						
Duration of flaming after first Application	s						
Duration of flaming plus glowing After second application	s						
Specimen burns to holding clamp	Yes/No						
Cotton ignited	Yes/No						
Sample result	Pass/Fail						

Supplementary information:

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

9.4	**TABLE: Limited-energy circuit**				**Form A.24**	N/A
Item or Location (see Form A.22)	9.4 a) Maximum potential in circuit voltage r.m.s./d.c. [V]	9.4 b) Current limitation (NOTE) Maximum available current [A]	Overload protection after 120 s [A]	9.4 c) Circuit separation	Decision Yes/No	Comments

NOTE – Maximum values see Tables 17 and 18 of IEC 61010-1

Supplementary information:

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

9.5	**TABLE: Requirements for equipment containing or using flammable liquids** **Form A.25**		N/A
Type of liquid	9.5 Flammable liquids		Verdict
	b) Quantity	c) Containment	
Supplementary information:			

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
198 V~, 60 Hz, Normal operating condition, Test duration: 2:52:00, Ambient: 22.5 ℃					
Power cord body	28.8	46.3	100	P	
Main switch	33.5	51.0	85	P	
Fuse holder with inlet	41.8	59.3	85	P	
AC wire	41.4	58.9	-	-	
Noise filter body	41.8	59.3	-	-	
Surge Protector body	43.2	60.7	-	-	
Terminal block (Mains parts)	41.8	59.3	105	P	
Terminal block (CN1) on the SSR board	42.9	60.4	105	P	
Varistor body (VA1) on the SSR board	59.5	77.0	-	-	
Solid state Relay (U2) on the SSR board	73.6	91.1	-	-	
Relay (U3) on the SSR board	51.4	68.9	-	-	
PCB on the SSR board	57.0	74.5	130	P	
Transformer (T1) coli on the SMPS	57.1	74.6	105	P	
Transformer (T1) core on the SMPS	55.0	72.5	105	P	
IC (U1) on the Main board	51.3	68.8	-	-	
PCB on the Main board	46.3	63.8	130	P	
Coin battery (Bat1) on the LCD display board	56.5	74.0	-	-	
PCB on the LCD display board	57.2	74.7	130	P	
Chamber internal metal case near Heater	56.0	73.5	-	-	
Bi-metal body on the Chamber	54.9	72.4	-	-	
Relay (RL8) on the CTR board	54.3	71.8	-	-	
PCB on the CTR board	53.8	71.3	130	P	
High voltage Transformer body	45.2	62.7	105	P	

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
PCB on the High voltage board	45.0	62.5	130	P	
d.c. motor body	53.4	70.9	-	-	
Solenoid valve body	73.1	90.6	-	-	
d.c. fan body on the Main unit	48.5	66.0	-	-	
a.c. fan body on the Pump module	64.2	81.7	-	-	
a.c. fan body on the Pump module	62.8	80.3	-	-	
AC pump body	22.8	40.3	-	-	
Plastic enclosure Front (Main unit)	30.9	48.4	-	-	
Plastic enclosure Back (Main unit)	37.6	55.1	85	P	
Plastic enclosure Right side (Main unit)	35.1	52.6	85	P	
Plastic enclosure Left side (Main unit)	40.8	58.3	85	P	
Plastic enclosure Upper (Main unit)	36.7	54.2	85	P	
Plastic enclosure Rear (Main unit)	27.6	45.1	85	P	
LCD display (Main unit)	31.3	48.8	85	P	
Plastic enclosure (Pump module)	37.7	55.2	85	P	
Non-detachable Power cord body	32.7	50.2	85	P	
Ambient	22.5	40.0	-	-	
264 V~, 50 Hz, Normal operating condition, Test duration: 1:38:00, Ambient: 23.6 ℃					
Power cord body	27.8	44.2	100	P	
Main switch	32.6	49.0	85	P	
Fuse holder with inlet	32.6	49.0	85	P	
AC wire	40.9	57.3	-	-	
Noise filter body	42.2	58.6	-	-	

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
Surge Protector body	43.5	59.9	-	-	
Terminal block (Mains parts)	41.9	58.3	105	P	
Terminal block (CN1) on the SSR board	41.7	58.1	105	P	
Varistor body (VA1) on the SSR board	54.7	71.1	-	-	
Solid state Relay (U2) on the SSR board	62.7	79.1	-	-	
Relay (U3) on the SSR board	48.7	65.1	-	-	
PCB on the SSR board	52.9	69.3	130	P	
Transformer (T1) coli on the SMPS	59.3	75.7	105	P	
Transformer (T1) core on the SMPS	56.8	73.2	105	P	
IC (U1) on the Main board	51.6	68.0	-	-	
PCB on the Main board	46.6	63.0	130	P	
Coin battery (Bat1) on the LCD display board	56.7	73.1	-	-	
PCB on the LCD display board	57.3	73.7	130	P	
Chamber internal metal case near Heater	55.9	72.3	-	-	
Bi-metal body on the Chamber	54.8	71.2	-	-	
Relay (RL8) on the CTR board	54.6	71.0	-	-	
PCB on the CTR board	54.6	71.0	130	P	
High voltage Transformer body	46.9	63.3	105	P	
PCB on the High voltage board	46.3	62.7	130	P	
d.c. motor body	53.5	69.9	-	-	
Solenoid valve body	74.0	90.4	-	-	
d.c. fan body on the Main unit	48.6	65.0	-	-	
a.c. fan body on the Pump module	74.9	91.3	-	-	

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
a.c. fan body on the Pump module	63.1	79.5	-	-	
AC pump body	23.6	40.0	-	-	
Plastic enclosure Front (Main unit)	31.2	47.6	-	-	
Plastic enclosure Back (Main unit)	38.2	54.6	85	P	
Plastic enclosure Right side (Main unit)	34.9	51.3	85	P	
Plastic enclosure Left side (Main unit)	41.4	57.8	85	P	
Plastic enclosure Upper (Main unit)	37.5	53.9	85	P	
Plastic enclosure Rear (Main unit)	28.3	44.7	85	P	
LCD display (Main unit)	31.2	47.6	85	P	
Plastic enclosure (Pump module)	40.2	56.6	85	P	
Non-detachable Power cord body	35.8	52.2	85	P	
Ambient	23.6	40.0	-	-	
264 V~, 50 Hz, Abnormal operating condition (Protective conductor open), Test duration: 1:36:00, Ambient: 23.2 ℃					
Power cord body	28.6	45.4	105	P	Protective conductor open
Main switch	33.2	50.0	105	P	
Fuse holder with inlet	33.3	50.1	105	P	
AC wire	41.6	58.4	-	-	
Noise filter body	43.1	59.9	-	-	
Surge Protector body	44.2	61.0	-	-	
Terminal block (Mains parts)	42.4	59.2	105	P	
Terminal block (CN1) on the SSR board	42.4	59.2	105	P	
Varistor body (VA1) on the SSR board	55.7	72.5	-	-	

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
Solid state Relay (U2) on the SSR board	63.6	80.4	-	-	
Relay (U3) on the SSR board	49.5	66.3	-	-	
PCB on the SSR board	53.7	70.5	130	P	
Transformer (T1) coli on the SMPS	59.7	76.5	150	P	
Transformer (T1) core on the SMPS	57.2	74.0	150	P	
IC (U1) on the Main board	52.0	68.8	-	-	
PCB on the Main board	47.1	63.9	130	P	
Coin battery (Bat1) on the LCD display board	57.2	74.0	-	-	
PCB on the LCD display board	57.7	74.5	130	P	
Chamber internal metal case near Heater	55.7	72.5	-	-	
Bi-metal body on the Chamber	54.7	71.5	-	-	
Relay (RL8) on the CTR board	55.4	72.2	-	-	
PCB on the CTR board	55.1	71.9	130	P	
High voltage Transformer body	47.4	64.2	150	P	
PCB on the High voltage board	46.9	63.7	130	P	
d.c. motor body	53.7	70.5	-	-	
Solenoid valve body	73.0	89.8	-	-	
d.c. fan body on the Main unit	49.3	66.1	-	-	
a.c. fan body on the Pump module	76.1	92.9	-	-	
a.c. fan body on the Pump module	63.3	80.1	-	-	
AC pump body	23.3	40.1	-	-	
Plastic enclosure Front (Main unit)	31.9	48.7	-	-	
Plastic enclosure Back (Main unit)	38.6	55.4	105	P	

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
Plastic enclosure Right side (Main unit)	35.4	52.2	105	P	
Plastic enclosure Left side (Main unit)	41.8	58.6	105	P	
Plastic enclosure Upper (Main unit)	37.4	54.2	105	P	
Plastic enclosure Rear (Main unit)	28.7	45.5	105	P	
LCD display (Main unit)	34.9	51.7	105	P	
Plastic enclosure (Pump module)	40.3	57.1	105	P	
Non-detachable Power cord body	36.0	52.8	105	P	
Ambient	23.2	40.0	-	-	
264 V~, 50 Hz, Abnormal operating condition (Output short), Test duration: 1:06:00, Ambient: 19.2 ℃					
Power cord body	23.4	44.2	105	P	Output short
Main switch	27.1	47.9	105	P	
Fuse holder with inlet	25.9	46.7	105	P	
AC wire	32.7	53.5	-	-	
Noise filter body	34.6	55.4	-	-	
Surge Protector body	34.3	55.1	-	-	
Terminal block (Mains parts)	32.9	53.7	105	P	
Terminal block (CN1) on the SSR board	30.7	51.5	105	P	
Varistor body (VA1) on the SSR board	31.7	52.5	-	-	
Solid state Relay (U2) on the SSR board	31.8	52.6	-	-	
Relay (U3) on the SSR board	31.3	52.1	-	-	
PCB on the SSR board	33.2	54.0	130	P	
Transformer (T1) coli on the SMPS	46.9	67.7	150	P	

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
Transformer (T1) core on the SMPS	44.7	65.5	150	P	
IC (U1) on the Main board	43.2	64.0	-	-	
PCB on the Main board	38.4	59.2	130	P	
Coin battery (Bat1) on the LCD display board	47.4	68.2	-	-	
PCB on the LCD display board	43.8	64.6	130	P	
Chamber internal metal case near Heater	39.7	60.5	-	-	
Bi-metal body on the Chamber	39.1	59.9	-	-	
Relay (RL8) on the CTR board	35.2	56.0	-	-	
PCB on the CTR board	41.0	61.8	130	P	
High voltage Transformer body	38.6	59.4	150	P	
PCB on the High voltage board	37.3	58.1	130	P	
d.c. motor body	38.3	59.1	-	-	
Solenoid valve body	35.4	56.2	-	-	
d.c. fan body on the Main unit	36.7	57.5	-	-	
a.c. fan body on the Pump module	34.9	55.7	-	-	
a.c. fan body on the Pump module	51.3	72.1	-	-	
AC pump body	51.5	72.3	-	-	
Plastic enclosure Front (Main unit)	27.3	48.1	-	-	
Plastic enclosure Back (Main unit)	29.6	50.4	105	P	
Plastic enclosure Right side (Main unit)	22.3	43.1	105	P	
Plastic enclosure Left side (Main unit)	30.7	51.5	105	P	
Plastic enclosure Upper (Main unit)	28.8	49.6	105	P	
Plastic enclosure Rear (Main unit)	24.5	45.3	105	P	

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
LCD display (Main unit)	25.5	46.3	105	P	
Plastic enclosure (Pump module)	31.5	52.3	105	P	
Non-detachable Power cord body	22.5	43.3	105	P	
Ambient	19.2	40.0	-	-	
264 V~, 50 Hz, Abnormal operating condition (Ventilation block), Test duration: 1:36:00, Ambient: 23.9 ℃					
Power cord body	30.4	46.5	105	P	Ventilation block
Main switch	35.9	52.0	105	P	
Fuse holder with inlet	39.1	55.2	105	P	
AC wire	42.8	58.9	-	-	
Noise filter body	42.4	58.5	-	-	
Surge Protector body	42.3	58.4	-	-	
Terminal block (Mains parts)	42.6	58.7	105	P	
Terminal block (CN1) on the SSR board	41.3	57.4	105	P	
Varistor body (VA1) on the SSR board	53.6	69.7	-	-	
Solid state Relay (U2) on the SSR board	61.5	77.6	-	-	
Relay (U3) on the SSR board	47.4	63.5	-	-	
PCB on the SSR board	52.0	68.1	130	P	
Transformer (T1) coli on the SMPS	57.8	73.9	150	P	
Transformer (T1) core on the SMPS	55.7	71.8	150	P	
IC (U1) on the Main board	51.9	68.0	-	-	
PCB on the Main board	46.8	62.9	130	P	
Coin battery (Bat1) on the LCD display board	55.9	72.0	-	-	
PCB on the LCD display board	57.5	73.6	130	P	
Chamber internal metal case near Heater	55.3	71.4	-	-	

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
Bi-metal body on the Chamber	54.4	70.5	-	-	
Relay (RL8) on the CTR board	55.1	71.2	-	-	
PCB on the CTR board	53.9	70.0	130	P	
High voltage Transformer body	42.9	59.0	150	P	
PCB on the High voltage board	43.6	59.7	130	P	
d.c. motor body	54.0	70.1	-	-	
Solenoid valve body	75.3	91.4	-	-	
d.c. fan body on the Main unit	52.3	68.4	-	-	
a.c. fan body on the Pump module	81.4	97.5	-	-	
a.c. fan body on the Pump module	70.2	86.3	-	-	
AC pump body	68.0	84.1	-	-	
Plastic enclosure Front (Main unit)	32.4	48.5	-	-	
Plastic enclosure Back (Main unit)	43.6	59.7	105	P	
Plastic enclosure Right side (Main unit)	36.0	52.1	105	P	
Plastic enclosure Left side (Main unit)	40.8	56.9	105	P	
Plastic enclosure Upper (Main unit)	38.4	54.5	105	P	
Plastic enclosure Rear (Main unit)	28.9	45.0	105	P	
LCD display (Main unit)	35.0	51.1	105	P	
Plastic enclosure (Pump module)	43.2	59.3	105	P	
Non-detachable Power cord body	46.0	62.1	105	P	
Ambient	23.9	40.0	-	-	
264 V~, 50 Hz, Abnormal operating condition (Main unit Fan lock), Test duration: 1:52:00, Ambient: 21.1 ℃					
Power cord body	27.5	46.4	105	P	Main unit Fan lock

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
Main switch	33.9	52.8	105	P	
Fuse holder with inlet	36.1	55.0	105	P	
AC wire	42.9	61.8	-	-	
Noise filter body	41.5	60.4	-	-	
Surge Protector body	41.4	60.3	-	-	
Terminal block (Mains parts)	43.1	62.0	105	P	
Terminal block (CN1) on the SSR board	40.2	59.1	105	P	
Varistor body (VA1) on the SSR board	53.9	72.8	-	-	
Solid state Relay (U2) on the SSR board	62.8	81.7	-	-	
Relay (U3) on the SSR board	48.2	67.1	-	-	
PCB on the SSR board	53.5	72.4	130	P	
Transformer (T1) coli on the SMPS	58.9	77.8	150	P	
Transformer (T1) core on the SMPS	56.4	75.3	150	P	
IC (U1) on the Main board	50.4	69.3	-	-	
PCB on the Main board	45.3	64.2	130	P	
Coin battery (Bat1) on the LCD display board	55.2	74.1	-	-	
PCB on the LCD display board	55.8	74.7	130	P	
Chamber internal metal case near Heater	55.6	74.5	-	-	
Bi-metal body on the Chamber	54.7	73.6	-	-	
Relay (RL8) on the CTR board	52.8	71.7	-	-	
PCB on the CTR board	52.9	71.8	130	P	
High voltage Transformer body	46.7	65.6	150	P	
PCB on the High voltage board	46.3	65.2	130	P	
d.c. motor body	53.8	72.7	-	-	

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
Solenoid valve body	76.2	95.1	-	-	
d.c. fan body on the Main unit	53.7	72.6	-	-	
a.c. fan body on the Pump module	71.5	90.4	-	-	
a.c. fan body on the Pump module	58.7	77.6	-	-	
AC pump body	23.6	42.5	-	-	
Plastic enclosure Front (Main unit)	29.1	48.0	-	-	
Plastic enclosure Back (Main unit)	38.0	56.9	105	P	
Plastic enclosure Right side (Main unit)	33.5	52.4	105	P	
Plastic enclosure Left side (Main unit)	37.0	55.9	105	P	
Plastic enclosure Upper (Main unit)	34.8	53.7	105	P	
Plastic enclosure Rear (Main unit)	26.6	45.5	105	P	
LCD display (Main unit)	34.1	53.0	105	P	
Plastic enclosure (Pump module)	38.7	57.6	105	P	
Non-detachable Power cord body	30.1	49.0	105	P	
Ambient	21.1	40.0	-	-	
264 V~, 50 Hz, Abnormal operating condition(Pump module Fan lock), Test duration: 1:44:00, Ambient: 20.6 ℃					
Power cord body	27.0	46.4	105	P	Pump module Fan lock
Main switch	31.6	51.0	105	P	
Fuse holder with inlet	31.2	50.6	105	P	
AC wire	40.4	59.8	-	-	
Noise filter body	42.3	61.7	-	-	
Surge Protector body	42.9	62.3	-	-	

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
Terminal block (Mains parts)	41.2	60.6	105	P	
Terminal block (CN1) on the SSR board	40.8	60.2	105	P	
Varistor body (VA1) on the SSR board	54.2	73.6	-	-	
Solid state Relay (U2) on the SSR board	62.2	81.6	-	-	
Relay (U3) on the SSR board	48.2	67.6	-	-	
PCB on the SSR board	52.3	71.7	130	P	
Transformer (T1) coli on the SMPS	58.2	77.6	150	P	
Transformer (T1) core on the SMPS	55.6	75.0	150	P	
IC (U1) on the Main board	50.7	70.1	-	-	
PCB on the Main board	45.7	65.1	130	P	
Coin battery (Bat1) on the LCD display board	55.9	75.3	-	-	
PCB on the LCD display board	56.4	75.8	130	P	
Chamber internal metal case near Heater	55.6	75.0	-	-	
Bi-metal body on the Chamber	54.4	73.8	-	-	
Relay (RL8) on the CTR board	53.7	73.1	-	-	
PCB on the CTR board	52.7	72.1	130	P	
High voltage Transformer body	46.1	65.5	150	P	
PCB on the High voltage board	45.2	64.6	130	P	
d.c. motor body	53.4	72.8	-	-	
Solenoid valve body	72.9	92.3	-	-	
d.c. fan body on the Main unit	48.3	67.7	-	-	
a.c. fan body on the Pump module	81.6	101.0	-	-	
a.c. fan body on the Pump module	60.8	80.2	-	-	

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
AC pump body	60.2	79.6	-	-	
Plastic enclosure Front (Main unit)	29.6	49.0	-	-	
Plastic enclosure Back (Main unit)	37.0	56.4	105	P	
Plastic enclosure Right side (Main unit)	33.4	52.8	105	P	
Plastic enclosure Left side (Main unit)	37.8	57.2	105	P	
Plastic enclosure Upper (Main unit)	35.0	54.4	105	P	
Plastic enclosure Rear (Main unit)	27.0	46.4	105	P	
LCD display (Main unit)	33.2	52.6	105	P	
Plastic enclosure (Pump module)	38.8	58.2	105	P	
Non-detachable Power cord body	33.3	52.7	105	P	
Ambient	20.6	40.0	-	-	
264 V~, 50 Hz, Abnormal operating condition (Pump module AC Fan lock), Test duration: 3:28:00, Ambient: 19.8 ℃					
Power cord body	25.1	45.3	105	P	Pump module AC Fan lock
Main switch	30.3	50.5	105	P	
Fuse holder with inlet	29.5	49.7	105	P	
AC wire	39.2	59.4	-	-	
Noise filter body	39.2	59.4	-	-	
Surge Protector body	40.3	60.5	-	-	
Terminal block (Mains parts)	39.8	60.0	105	P	
Terminal block (CN1) on the SSR board	38.0	58.2	105	P	
Varistor body (VA1) on the SSR board	48.7	68.9	-	-	
Solid state Relay (U2) on the SSR board	54.5	74.7	-	-	

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
Relay (U3) on the SSR board	43.5	63.7	-	-	
PCB on the SSR board	47.4	67.6	130	P	
Transformer (T1) coli on the SMPS	57.8	78.0	150	P	
Transformer (T1) core on the SMPS	55.2	75.4	150	P	
IC (U1) on the Main board	48.6	68.8	-	-	
PCB on the Main board	43.5	63.7	130	P	
Coin battery (Bat1) on the LCD display board	54.1	74.3	-	-	
PCB on the LCD display board	54.7	74.9	130	P	
Chamber internal metal case near Heater	56.0	76.2	-	-	
Bi-metal body on the Chamber	54.0	74.2	-	-	
Relay (RL8) on the CTR board	53.0	73.2	-	-	
PCB on the CTR board	52.2	72.4	130	P	
High voltage Transformer body	43.6	63.8	150	P	
PCB on the High voltage board	43.0	63.2	130	P	
d.c. motor body	52.5	72.7	-	-	
Solenoid valve body	70.9	91.1	-	-	
d.c. fan body on the Main unit	45.7	65.9	-	-	
a.c. fan body on the Pump module	79.3	99.5	-	-	
a.c. fan body on the Pump module	54.3	74.5	-	-	
AC pump body	75.8	96.0	-	-	
Plastic enclosure Front (Main unit)	29.0	49.2	-	-	
Plastic enclosure Back (Main unit)	33.3	53.5	105	P	
Plastic enclosure Right side (Main unit)	28.4	48.6	105	P	

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
Plastic enclosure Left side (Main unit)	39.8	60.0	105	P	
Plastic enclosure Upper (Main unit)	35.5	55.7	105	P	
Plastic enclosure Rear (Main unit)	26.0	46.2	105	P	
LCD display (Main unit)	33.3	53.5	105	P	
Plastic enclosure (Pump module)	46.0	66.2	105	P	
Non-detachable Power cord body	27.7	47.9	105	P	
Ambient	19.8	40.0	-	-	
264 V~, 50 Hz, Abnormal operating condition (Heater Bi-metal open), Test duration: 1:20:00, Ambient: 22.3 ℃					
Power cord body	27.9	45.6	105	P	Heater Bi-metal open
Main switch	31.6	49.3	105	P	
Fuse holder with inlet	33.0	50.7	105	P	
AC wire	40.1	57.8	-	-	
Noise filter body	41.2	58.9	-	-	
Surge Protector body	41.5	59.2	-	-	
Terminal block (Mains parts)	40.6	58.3	105	P	
Terminal block (CN1) on the SSR board	39.6	57.3	105	P	
Varistor body (VA1) on the SSR board	52.2	69.9	-	-	
Solid state Relay (U2) on the SSR board	60.8	78.5	-	-	
Relay (U3) on the SSR board	46.5	64.2	-	-	
PCB on the SSR board	50.6	68.3	130	P	
Transformer (T1) coli on the SMPS	58.1	75.8	150	P	
Transformer (T1) core on the SMPS	55.7	73.4	150	P	
IC (U1) on the Main board	49.4	67.1	-	-	

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
PCB on the Main board	44.3	62.0	130	P	
Coin battery (Bat1) on the LCD display board	53.7	71.4	-	-	
PCB on the LCD display board	55.0	72.7	130	P	
Chamber internal metal case near Heater	53.9	71.6	-	-	
Bi-metal body on the Chamber	52.8	70.5	-	-	
Relay (RL8) on the CTR board	53.9	71.6	-	-	
PCB on the CTR board	52.0	69.7	130	P	
High voltage Transformer body	44.3	62.0	150	P	
PCB on the High voltage board	43.9	61.6	130	P	
d.c. motor body	52.1	69.8	-	-	
Solenoid valve body	71.4	89.1	-	-	
d.c. fan body on the Main unit	47.6	65.3	-	-	
a.c. fan body on the Pump module	76.1	93.8	-	-	
a.c. fan body on the Pump module	62.4	80.1	-	-	
AC pump body	60.8	78.5	-	-	
Plastic enclosure Front (Main unit)	30.0	47.7	-	-	
Plastic enclosure Back (Main unit)	31.7	49.4	105	P	
Plastic enclosure Right side (Main unit)	23.0	40.7	105	P	
Plastic enclosure Left side (Main unit)	41.5	59.2	105	P	
Plastic enclosure Upper (Main unit)	35.4	53.1	105	P	
Plastic enclosure Rear (Main unit)	28.4	46.1	105	P	
LCD display (Main unit)	26.7	44.4	105	P	
Plastic enclosure (Pump module)	40.6	58.3	105	P	

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
Non-detachable Power cord body	32.6	50.3	105	P	
Ambient	22.3	40.0	-	-	
264 V~, 50 Hz, Abnormal operating condition (Heater Bi-metal short), Test duration: 1:43:00, Ambient: 19.5 ℃					
Power cord body	26.9	47.4	105	P	Heater Bi-metal short
Main switch	32.5	53.0	105	P	
Fuse holder with inlet	32.3	52.8	105	P	
AC wire	40.1	60.6	-	-	
Noise filter body	41.3	61.8	-	-	
Surge Protector body	42.1	62.6	-	-	
Terminal block (Mains parts)	40.8	61.3	105	P	
Terminal block (CN1) on the SSR board	39.7	60.2	105	P	
Varistor body (VA1) on the SSR board	52.0	72.5	-	-	
Solid state Relay (U2) on the SSR board	59.0	79.5	-	-	
Relay (U3) on the SSR board	45.8	66.3	-	-	
PCB on the SSR board	50.2	70.7	130	P	
Transformer (T1) coli on the SMPS	59.1	79.6	150	P	
Transformer (T1) core on the SMPS	56.5	77.0	150	P	
IC (U1) on the Main board	50.7	71.2	-	-	
PCB on the Main board	45.7	66.2	130	P	
Coin battery (Bat1) on the LCD display board	56.1	76.6	-	-	
PCB on the LCD display board	57.0	77.5	130	P	
Chamber internal metal case near Heater	56.3	76.8	-	-	
Bi-metal body on the Chamber	54.4	74.9	-	-	

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
Relay (RL8) on the CTR board	54.3	74.8	-	-	
PCB on the CTR board	53.9	74.4	130	P	
High voltage Transformer body	45.7	66.2	150	P	
PCB on the High voltage board	45.3	65.8	130	P	
d.c. motor body	53.3	73.8	-	-	
Solenoid valve body	71.7	92.2	-	-	
d.c. fan body on the Main unit	46.9	67.4	-	-	
a.c. fan body on the Pump module	77.6	98.1	-	-	
a.c. fan body on the Pump module	63.1	83.6	-	-	
AC pump body	62.7	83.2	-	-	
Plastic enclosure Front (Main unit)	30.4	50.9	-	-	
Plastic enclosure Back (Main unit)	37.6	58.1	105	P	
Plastic enclosure Right side (Main unit)	21.8	42.3	105	P	
Plastic enclosure Left side (Main unit)	42.4	62.9	105	P	
Plastic enclosure Upper (Main unit)	35.6	56.1	105	P	
Plastic enclosure Rear (Main unit)	27.1	47.6	105	P	
LCD display (Main unit)	34.8	55.3	105	P	
Plastic enclosure (Pump module)	40.5	61.0	105	P	
Non-detachable Power cord body	32.1	52.6	105	P	
Ambient	19.5	40.0	-	-	

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

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

10.	**TABLE: Temperature Measurements** **Form A.26A**	P
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION	P
10.3	Other temperature measurements	P

Operating conditions:	Operating condition: Sterilize mode, continuous operating		
Frequency..... :	(See below)	Test room ambient temperature (ta) ...:	(See below)
Voltage..... :	(See below)	Test duration .....:	(See below)

Part / Location	t_m [°C]	t_c [°C]	t_{max} [°C]	Verdict	Comments
Supplementary information:					

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

10.2	**TABLE: Temperature of windings** **Form A.26B** **Resistance method Temperature Measurements**	N/A
4.4.2.7	MAINS transformers	N/A
14.2.1	Motor temperatures	N/A

Operating conditions..:								
Frequency.....:	Hz	Test room ambient temperature (ta1/ta2)..:					/	°C (initial / final)
Voltage.....:	V	Test duration.....:					h	min
Part / Designation	Rcold [Ω]	Rwarm [Ω]	Current [A]	t_r [K]	t_c [°C]	t_{max} [°C]	Verdict	Comments

NOTE 1- R_{cold} = initial resistance
t_r = temperature rise
t_{max} = maximum permitted temperature
R_{warm} = final resistance
t_c = t_r corrected (t_c= t_r + [40 °C or max RATED ambient])
NOTE 2 - Indicate insulation class (IEC 60085) under comments (optional)
NOTE 3 - Record values for NORMAL CONDITION and / or SINGLE FAULT CONDITION in this Form use additional form if necessary

Supplementary information:

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

10.5.2	**TABLE: Resistance to heat of non-metallic ENCLOSURES**				**Form A.27** P
	Test method used:				—
	Non-operative treatment ..... :	[V]			P
	Empty ENCLOSURE ..... :	[ ]			N/A
	Operative treatment ..... :	[ ]			N/A
	Temperature during tests..... :	70 °C, 7 h			—
Description	Material	Comments			Verdict
Enclosure	Plastic	No damage, No hazard			P
Dielectric strength test (6.8) ..... :		3 000	V	[r.m.s./~~peak/d.c.~~]	P

NOTE – Within 10 minutes of the end of treatment suitable tests in acc. to 8.2 and 8.3 must be conducted and pass criteria of 8.1.

Supplementary information:
Cut-off current: 40 mA

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

10.5.3	**TABLE: Insulating material**	**Form A.28**	P
10.5.3 1)	Ball-pressure test		P
	Max. allowed impression diameter ..... :	2 mm	—

Part	Test temperature [°C]	Impression diameter [mm]	Verdict
AC connector (CN12) on the AC Relay MCU board	125	0.86	P
AC terminal block (CN17) on the AC Relay MCU board	125	1.10	P
AC terminal block in the Main unit	125	1.12	P

Supplementary information:

10.5.3 2)	**Vicat softening test (ISO 306)**	**Form A.29**	N/A

Part	Vicat softening temperature [°C]	Thickness of sample [mm]	Verdict

Supplementary information:

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

8	**TABLE: Mechanical resistance to shock and impact** **Form A.30**	P
11	**Protection against HAZARDS from fluids and solid foreign objects**	P

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.

Location (see Form A.14)	Clause 8 tests				Clause 11 tests				Working voltage [r.m.s./d.c.]	Test voltage [r.m.s./peak/d.c.]	Verdict	Comments
	Static (8.2.1) 30 N	Impact (8.2.2)	Normal (8.3.1)	Handheld Plug-in (8.3.2)	Cleaning (11.2)	Spillage (11.3)	Overflow (11.4)	IEC 60529 (11.6)				
A	P	P	P	-	P	-	-	-	240	1 500	P	
B	P	P	P	-	P	-	-	-	240	3 000	P	
C	P	P	P	-	P	-	-	-	240	3 000	P	
D	P	P	P	-	P	-	-	-	240	3 000	P	
E	P	P	P	-	P	-	-	-	240	3 000	P	

NOTE – Use r.m.s., d.c. or peak to indicate the used test voltage.

Supplementary information:
Cut-off current: 40 mA

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

11.7.2	TABLE: Leakage and rupture at high pressure	Form A.31	N/A

Part	Maximum permissible working pressure [MPa]	Test pressure [MPa]	Leakage Yes / No	Deformation Yes / No	Burst Yes / No	Comments

NOTE – see also Annex G with requirements for USA and Canada.

Supplementary information:

11.7.3	TABLE: Leakage from low-pressure parts	Form A.32	N/A

Part	Test pressure [MPa]	Leakage Yes / No	Comments

Supplementary information:

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

12.2.1	**TABLE: Ionizing radiation**		**Form A.33**	N/A
12.2.1.2	Equipment intended to emit radiation			
Locations tested	Measured values [µSv/h]	Verdict	Comments	
Supplementary information:				
12.2.1.3	**Equipment not intended to emit radiation**		**Form A.34**	N/A
	Max. allowed effective dose rate at 100 mm……:		1 µSv/h	—
Locations tested	Measured values [µSv/h]	Verdict	Comments	
Supplementary information:				

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

12.5.1	**TABLE: Sound level**	**Form A.35**	N/A

Locations tested	Measured maximum sound pressure level dB(A)	Calculated maximum sound power level
At operator's normal position and at bystanders' positions		
a)		
b)		
c)		
d)		
e)		
f)		

Supplementary information:

12.5.2	**TABLE: Ultrasonic pressure**	**Form A.36**	N/A

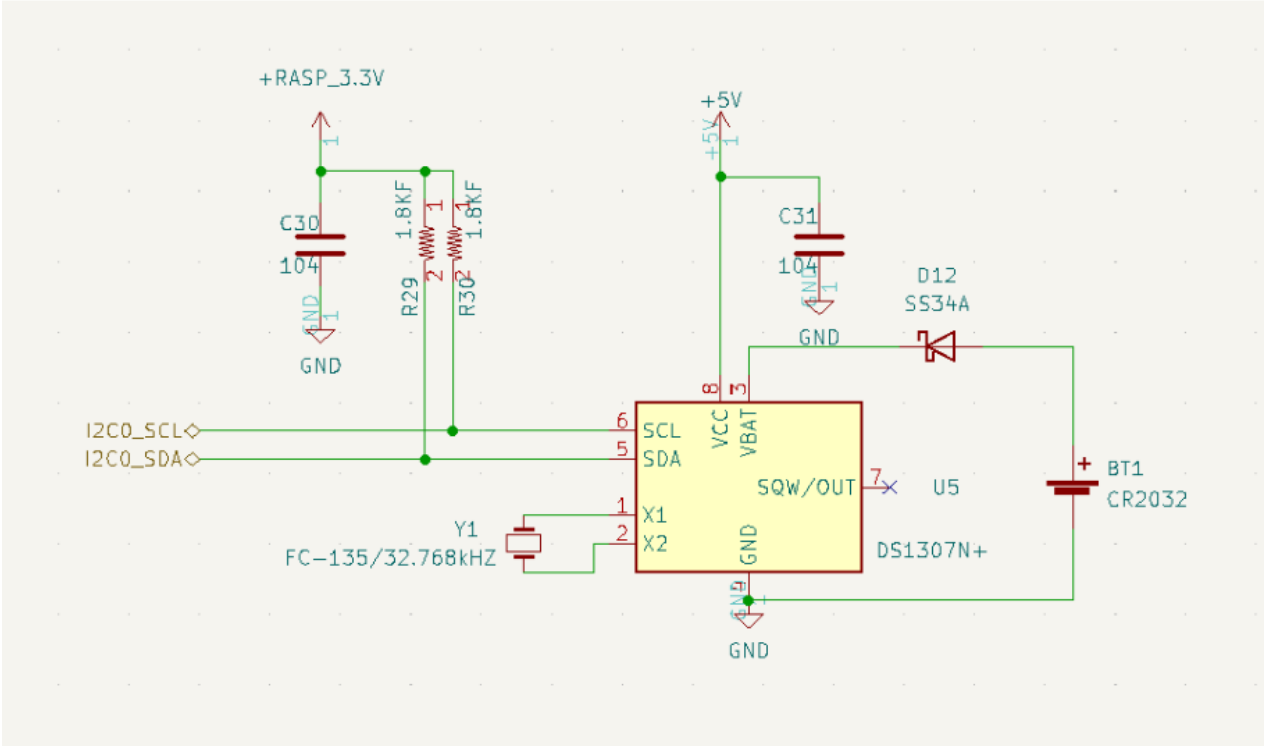
Locations tested	Measured values		Comments
	[dB]	[kHz]	
At operator's normal position			
At 1 m from the ENCLOSURE			
a)			
b)			
c)			
d)			
e)			

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.

Supplementary information:

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

13.2.2	**TABLE: Batteries and battery charging**	**Form A.37**	P
	Battery load and charging circuit diagram:		



	Battery type..... :	Coin battery	—
	Battery manufacturer/model/catalogue No. ..... :	Maxell / CR2032	—
	Battery ratings..... :	3.7 Vd.c., Abnormal charging current: 10 mA	—
	Reverse polarity instalment test	-	-

Single component failures	Verdict	
Component	Open circuit	Short circuit
Diode (D12)	-	10.25 uA
U5 (Pin 8 to Pin 3)	-	2.03 uA

Supplementary information:

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

14.3	**TABLE: Overtemperature protection devices**	**Form A.38**	N/A

Reliability test

Component	Type (NOTE)	Verdict	Comments

NOTE:
NSR = non-self-resetting (10 times)
NR = non-resetting (1 time)
SR = self-resetting (200 times)

Supplementary information:

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

4.4.2.7	**TABLE: MAINS transformer**				**Form A.39**	N/A
4.4.2.7.2	Short circuit					
14.6	MAINS transformers tested outside equipment					
Type ..... :						—
Manufacturer ..... :						—
Test in equipment						
Test on bench						
Test repeated inside equipment (see 14.6)						
Optional – Insulation class (IEC 60085) of the lowest rated winding ..... :						—
Winding identification						
Type of Protector for winding (NOTE 1)						
Elapsed time						
Current, A primary						
secondary						
Winding temperature, °C primary						
(see NOTE 2) secondary						
Tissue paper / cheesecloth OK ? (Pass / Fail)						
Voltage tests (see NOTE 3)						
Primary to secondary	_____ V ____					
Primary to core	_____ V ____					
Secondary to secondary	_____ V ____					
Secondary to core	_____ V ____					
Verdict						

NOTE 1: Primary fuse - PF / ( ) A
Secondary fuse - SF / ( ) A
Overtemperature protection - OP / ( ) °C
Impedance protection - Z

NOTE 2: Indicate method of measurement - TC = with thermocouple
- R = resistance method
If resistance method is used, record resistance in cold and warm condition in Form A.26B.

NOTE 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

Supplementary information:

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

4.4.2.7	**TABLE: MAINS transformer**				**Form A.40**	N/A
4.4.2.7.3	Overload tests (for MAINS transformers)					
14.6	MAINS transformers tested outside equipment					
Type .....:						—
Manufacturer .....:						—
Test in equipment						
Test on bench						
Test repeated inside equipment (see 14.6)						
Optional – Insulation class (IEC 60085) of the lowest rated winding .....:						—
Winding identification						
Type of Protector for winding (NOTE 1)						
Elapsed time						
Current, A primary						
secondary						
Winding temperature, °C primary						
(see NOTE 2) secondary						
Tissue paper / cheesecloth OK ? (Pass / Fail)						
Voltage tests (see NOTE 3)						
Primary to secondary	_____ V ____					
Primary to core	_____ V ____					
Secondary to secondary	_____ V ____					
Secondary to core	_____ V ____					
Verdict						

NOTE 1: Primary fuse - PF / ( ) A
Secondary fuse - SF / ( ) A
Overtemperature protection - OP / ( ) °C
Impedance protection - Z

NOTE 2: Indicate method of measurement TC = with thermocouple
R = resistance method
If resistance method is used, record resistance in cold and warm condition in Form A.26B.

NOTE 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

Supplementary information:

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

14.8	**TABLE: Circuits used to limit TRANSIENT OVERVOLTAGES**										**Form A.41**	N/A
Circuit / Designation	Overvoltage Category	MAINS voltage [V r.m.s.]	Test voltage [V]	t_m [°C]	t_c [°C]	t_{max} [°C]	Ignited Yes / No	Safely suppressed Yes / No	Properly functional Yes / No	Verdict	Comments	
Test room ambient temperature:		°C										

NOTE - t_m = measured temperature

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

t_{max} = maximum permitted temperature

Conformity is checked by applying 5 positive and 5 negative impulses with the applicable impulse withstand voltage, spaced up to 1 min apart, from a hybrid impulse generator (see IEC 61180-1).

Supplementary information:

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

Annex H	**TABLE: Qualification of conformal coating for protection against pollution**	**Form A.42**	N/A

Technical properties		
Manufacturer..... :		—
Type..... :		—
Meet requirements of ANSI / UL 746E ..... :	[yes / no]	
Manufacturer declaration of coating material :	[yes / no]	
Operating temperature of coating..... :	[ ] °C	
Comparative tracking index (CTI)..... :	[ ]	
Insulation resistance..... :	[ ] MΩ	
Dielectric strength..... :	[ ] V	
UV resistance (if required)..... :	[yes / no]	
Flammability rating ..... :		
Preparation of the test specimens conducted:	[yes / no]	

Item	Test conditioning	Parameter	Td	Samples						Verdict	Comments
			h	1	2	3	4	5	6		
1	Cold		24								
2	Dry heat		48								
3	Rapid temp. change										
4	Damp heat		24								
5	Adhesion of coating	5 N									
	Visual inspection										
6	Humidity		48								
7	Insulation resistance	≥ 100 MΩ									
	Visual inspection										

NOTE Td = Test duration time

Supplementary information:

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

	TABLE: Additional or special tests conducted	**Form A.43**	N/A
Clause and name of test	Test type and condition	Observed results	—
Supplementary information:			

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

	TABLE 1.A: 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)
	Power cord plug	Korea KDK Co., Ltd	KKP-4819D	250 V~, 16 A	IEC 60884-1:2002/AMD1:2006	CB (Intertek) / SE-59591
	Power cord Cable	Korea KDK Co., Ltd	H05VV-F	3 x 0.75 mm^2	EN 50525-2-11	VDE / 101928
	Power cord connector	Korea KDK Co., Ltd	KKS-16A	250 V~, 10 A	IEC 60320-1:2001/AMD1:2007	Intertek (CB) / SE-59708
	Noise filter	Dong Il technology Ltd	ES1-T10	250 V~, 10 A 2 x 3 300 pF (Y) 2 x 0.22 uF (X)	UL 1283 (Ed.7)	UL / E105227
	Surge protector	LS Industrial System	BK10S-T2	L-N: 385 V N-G: 385 V N-G: 255 V	ANSI/UL 1449, (Ed.5)	UL / E487006
	Appliance inlet with fuse holder	Inalways	0717-2SCQ	250 V~, 10 A	UL 60320-1 (Ed.3)	UL / E122965
	Main fuse	Little fuse	218 Series	250 V~, T10.0AL	IEC 60127-1:2006/AMD2:2015 IEC 60127-2:2014 ANSI/UL 248-1 (Ed.4)	VDE / 40013496 UL / E10480
	Primary and Ground wire	Shinwha Electric Wire Co., Ltd.	1015	600 V~, 105 ℃, 18 AWG	UL 758 (Ed.3)	UL / E97577
	Internal AC connector	Molex., com.	5557 Series (Part No.: 39012020) 5559 Series (Part No.: 39012021)	13 A, 105 ℃	UL 1977 (Ed.4)	UL / E29179

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

	TABLE 1.A: 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)
	Internal terminal block	Dong-A Bestech Co.,Ltd.	DFT-20A-8P	600 V~, 20 A	UL 60947-1 (Ed.6)	UL / E119716
	SMPS	Meanwell	LRS-200-24	Input: (100-240) V~, (4.0-2.0) A, (50/60) Hz Output: 24 Vd.c., 8.8 A	IEC 62368-1:2014	CB (UL Demko) / DK-88539-UL
	DC Solenoid Valve (Flow control valve)	Shinyeong Mechatronics Co., Ltd	QC200-5-4L	24 Vd.c., 9 W, 2.0 MPa	IEC 61010-1:2010/AMD1:2016	Tested in the Equipment
	DC Solenoid Valve (Flow control valve)	Yonwoo Pneumatic Co., Ltd.	SD1-D4	24 Vd.c., 2.5 W	IEC 61010-1:2010/AMD1:2016	Tested in the Equipment
	d.c. Fan	J. C. International Inc.	BFH5010S	12 Vd.c., 1.44 W	UL507 (Ed.10)	UL / E347107
	Plastic enclosure (Main unit)	LG chem Ltd.	AF312A	Min.Thick: 1.5 mm, 85 ℃, V-0	ANSI/UL 94 (Ed.6), UL 746B (Ed.5)	UL / E67171
	PCB (SSR Board, MCU Board, CTR Board, LCD Board)	Eunsung eleccom Co., Ltd.	2	V-0, 105 ℃	UL 796 (Ed.12)	UL / E207595
	Alternative PCB (SSR Board, MCU Board, CTR Board, LCD Board)	Shinseong SG Co., Ltd.	4	V-0, 130 ℃	UL 796 (Ed.12)	UL / E319731
	Heater thermostats	Seki control Co ltd	ST-22	250 V~, 1 A, 80 ℃	UL 60730-1 (Ed.5)	UL / E162183

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

	TABLE 1.A: 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)
	Upper, Lower heater	Innox advanced materials Co., Ltd.	MAH-(#)-(@)N($)	220 V~, 60 W, V-0, 130 ℃ Type film (200 x 80 mm)	ANSI/UL 94 (Ed.6), UL 746B (Ed.5)	UL / E239322
	Vaporizer heater (Main body)	Innox advanced materials Co., Ltd.	MAH-(#)-(@)N($)	24 Vd.c., 10 W Type film V-0, 130 ℃ (10 x 40 mm)	ANSI/UL 94 (Ed.6), UL 746B (Ed.5)	UL / E239322
	High voltage power supply	Plasmapp Co., Ltd.	BD1-0010-00	Input: (100-240) V~ Output: 5 kV	IEC 61010-1:2010/AMD1:2016	Tested in the Equipment
	Door switch	AUTONICS	BS5-V2M	(5-24) Vd.c., 30 mA	IEC 61010-1:2010/AMD1:2016	Tested in the Equipment
	LCD Panel	Clear display	CT070NL22-50ND-27D-CS	12 Vd.c., 500 mA , 7 inch 800 x 480 RGB	IEC 61010-1:2010/AMD1:2016	Tested in the Equipment
	Coin Battery in LCD board	Maxell, Ltd.	CR2032	3 Vd.c., Max. Abnormal charging current: 10 mA, Max. Abnormal charging voltage: 12 Vd.c	UL 1642 (Ed.6)	UL / MH12568
Description	SSR board					

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

	TABLE 1.A: 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)	
U1, U2	Relay	UNION ELECOM	PDA1-208Z	Input: (4-32) Vd.c., Output: 240 V~, 8 A	IEC 60158-2: 1982 EN 60947-4-1: A1+A2	TUV Rheinland / J02137522	
U3 to U16	Relay	IXYS Integrated Circuits Div	CPC1966Y	Input: 5 Vd.c. Output: 240 V~ Isolation voltage: 3 750 V~	UL 60947-1 (Ed.6)	UL / E69938	
VA1	Varistor	CNR	14D561	Measured Limiting voltage : 1 220 V~	UL1449 (Ed.4)	UL / E316325	
CN1	Terminal block	Dong-A Bestech Co.,Ltd.	DFT-20A-8P	600 V~, 20 A	UL 60947-1 (Ed.6)	UL / E119716	
Description	Pump module connected Main unit						
	Power cord Cable	Korea KDK Co.,Ltd	H05VV-F	3 x 0.75 mm^2	EN 50525-2-11	VDE / 101928	
	Power cord connector	Korea KDK Co.,Ltd	KKS-16A	250 V~, 10 A	IEC 60320-1:2001/AMD1:2007	Intertek (CB) / SE-59708	
Description	PUMP Module						
	Pump module AC Inlet	Inalways Electronic (Dongguan) Co.,Ltd.	0707-1	250 V~, 10 A	UL 60320-1 (Ed.3)	UL / E94191	
	AC pump	Pfeiffer Vacuum GmbH	PK D070 010 A0 A	(230 ± 10 %) V~ (50/60) Hz, (1.0-1.5) A	UL 61010-1:2012	TUV Rheinland / CU 72141357	

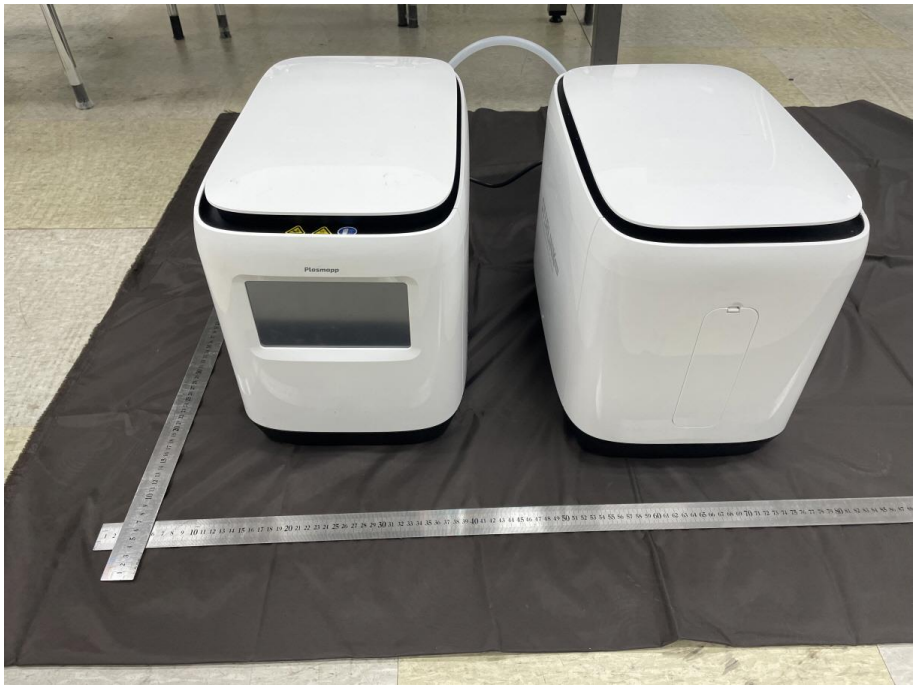
IEC 61010-1			
Clause	Requirement — Test	Result — Remark	Verdict

	TABLE 1.A: 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)	
	Plastic enclosure (Pump module)	LG chem Ltd.	AF312A	Min.Thick: 1.5 mm, 85 ℃, V-0	ANSI/UL 94 (Ed.6), UL 746B (Ed.5)	UL / E67171	
	AC Fan (Small)	COMMONWEALTH INDUSTRIAL CORPORATION	FP-108AX	(220/240) V~, (50/60) Hz, (13/14) W	UL507 (Ed.10)	UL / E89467	
	AC Fan (Big)		FP-108-1	(220/240) V~, (50/60) Hz, (18/17) W			
Description	Option						
	Printer	Woosim System Inc	PORTI-P240	5 Vd.c., (0.06-3) A	IEC 61010-1:2010/AMD1:2016	Tested in equipment	
	Printer Adaptor	Shenzhen Fujia Appliance Co., Ltd.	FJ-SW20260505000	Input: (100-240) V~, 1.5 A, (50-60) Hz Output: 5 Vd.c., 5 000 mA	EN 62368-1:2014+A11	TUV Rheinland / S 50474316	

NOTE → 1 List all different manufacturers of the above components → 4 asterisk indicates mark assuring agreed level of surveillance
→ 2 May include electrical, mechanical values
→ 3 List licence no or method of acceptance

Attachment 1 - Photographs

<Front side view Main unit with Pump module>



<Rear side view Main unit with Pump module>

Attachment 1 - Photographs

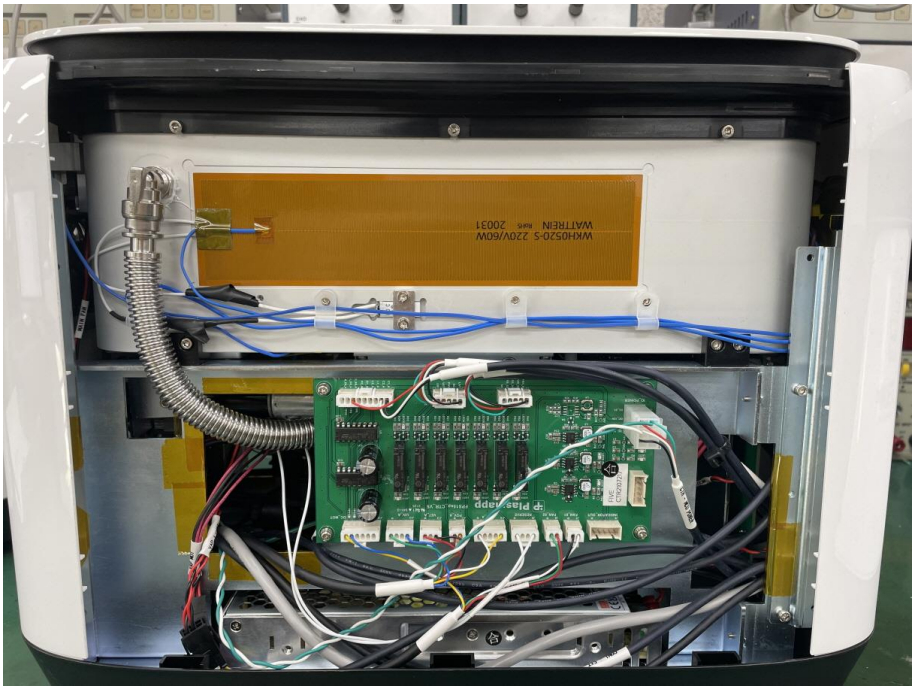
<Front side view Main unit>

<Rear side view Main unit>

Attachment 1 - Photographs

<Inside view Main unit_1>

<Inside view Main unit _2>



Attachment 1 - Photographs

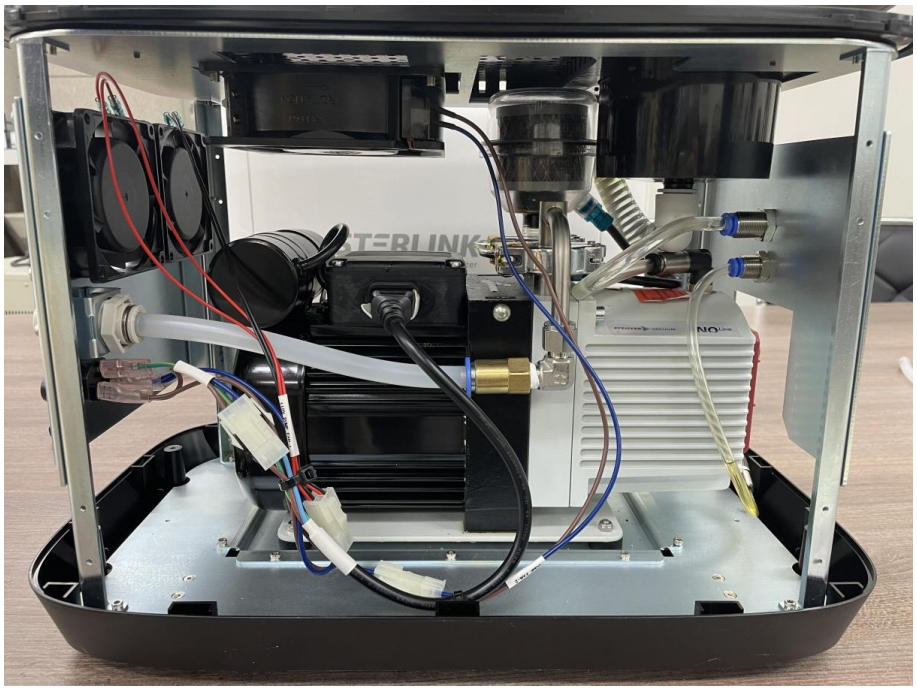
<Front side view Pump module>

<Rear side view Pump module >

Attachment 1 - Photographs

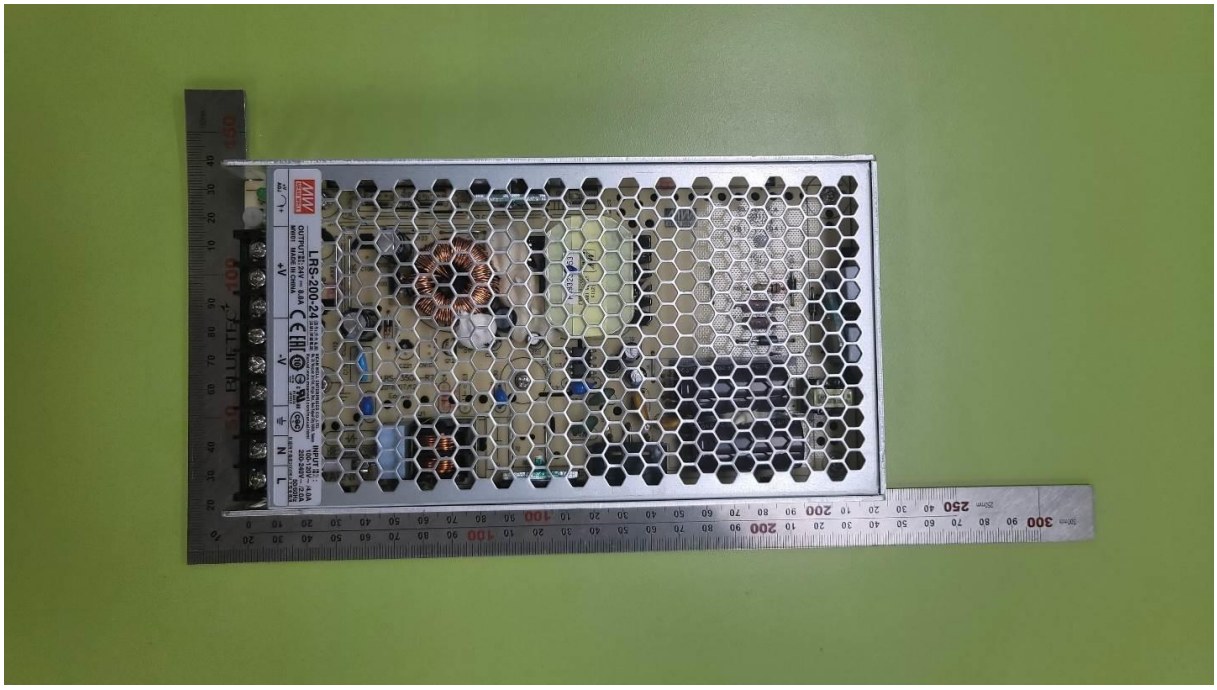
<Inside view Pump module_1>

<Inside view Pump module _2>

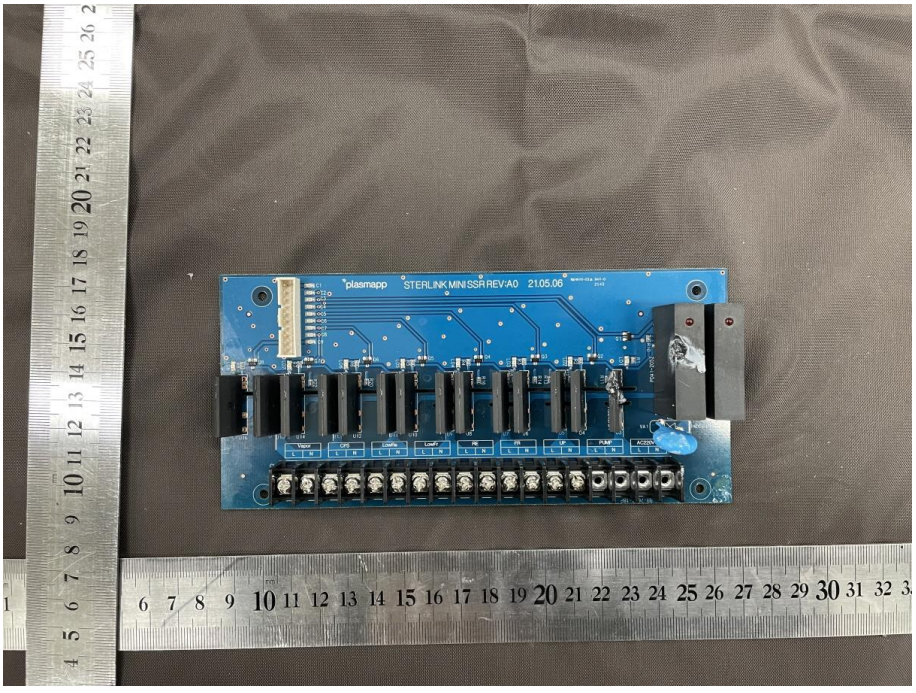


Attachment 1 - Photographs

<SMPS (Model: LRS-200-24)>

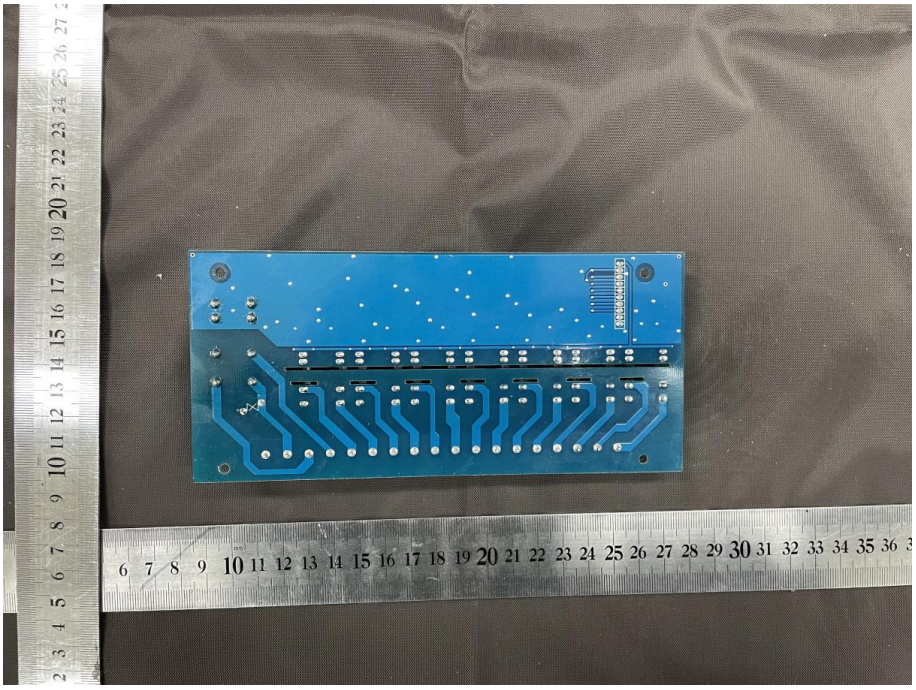


<Front side view SSR board>

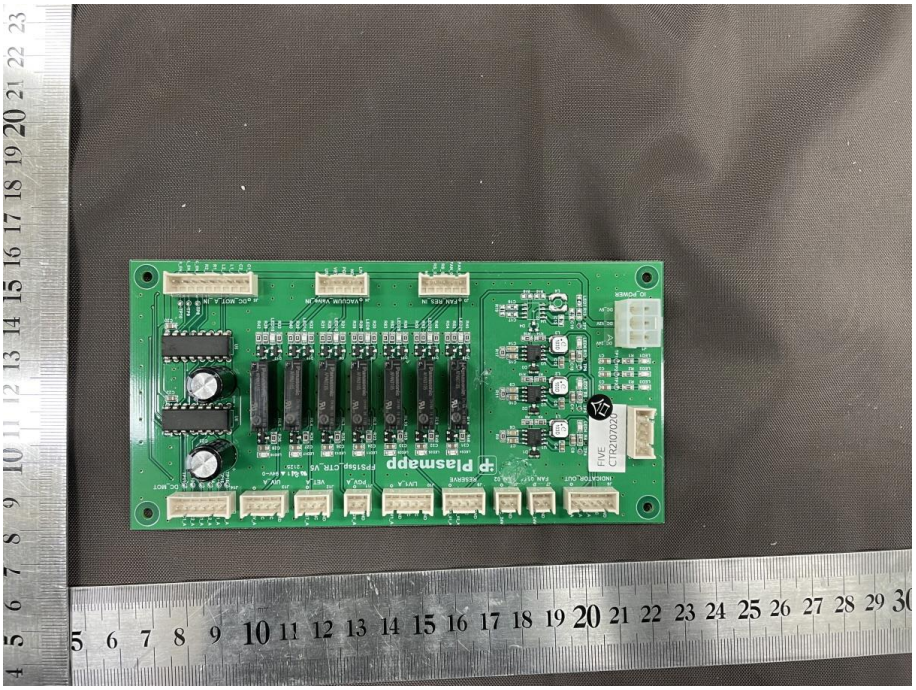


Attachment 1 - Photographs

<Rear side view SSR board>

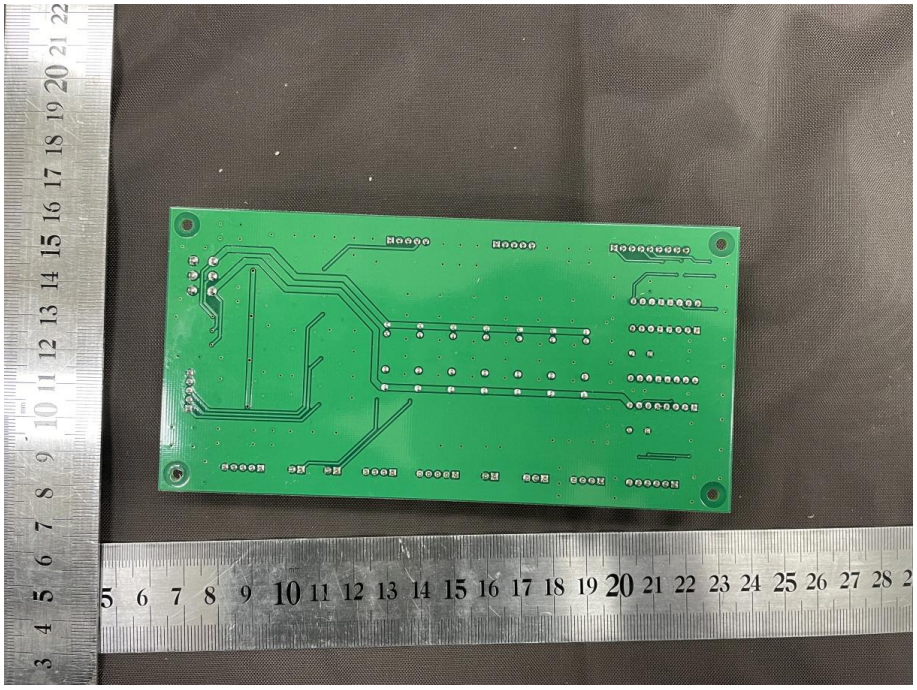


<Front side view CTR board>

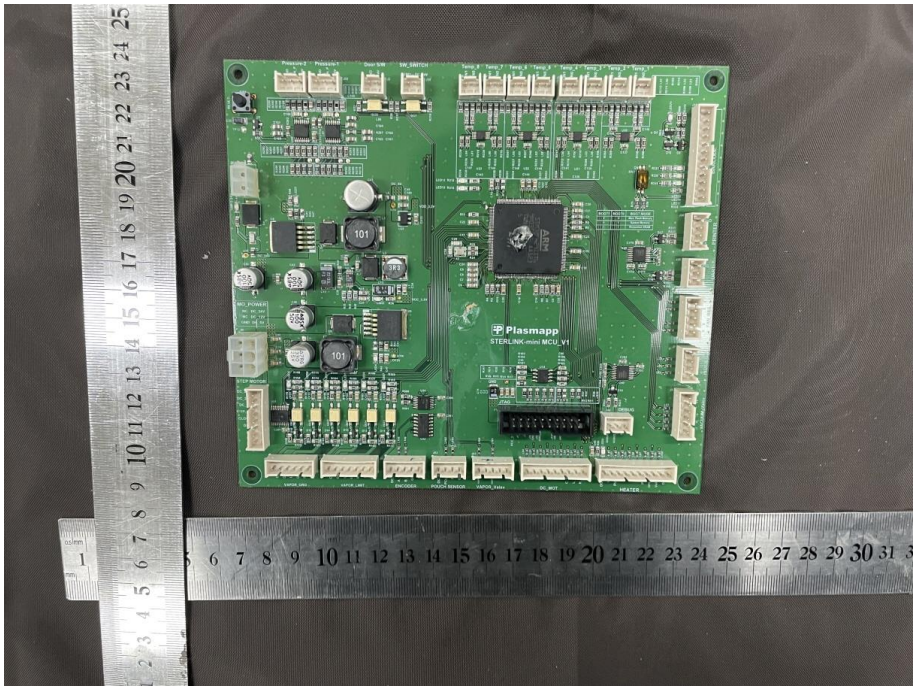


Attachment 1 - Photographs

<Rear side view CTR board>

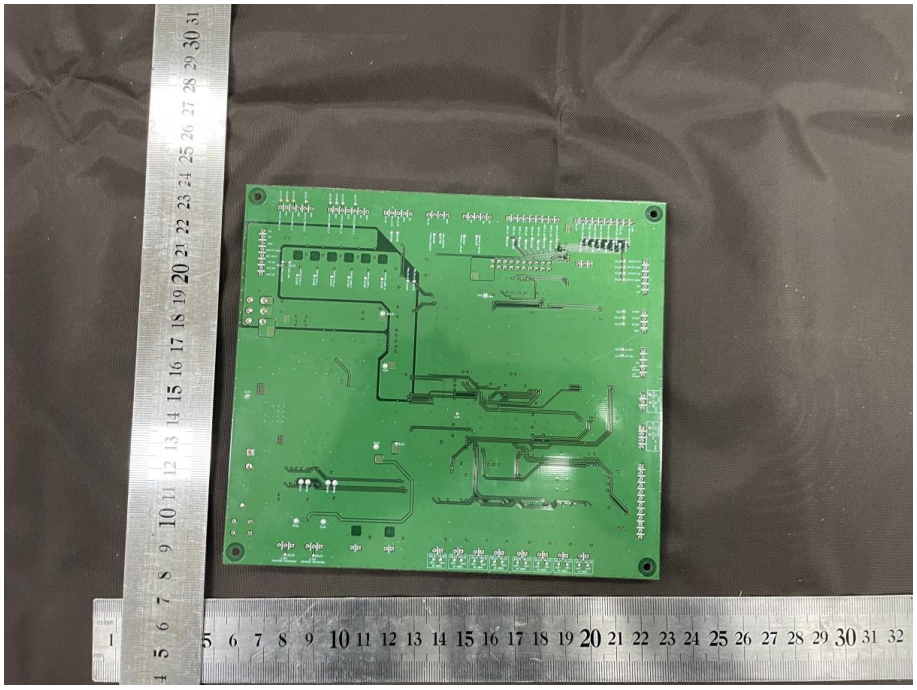


<Front side view Main control board>

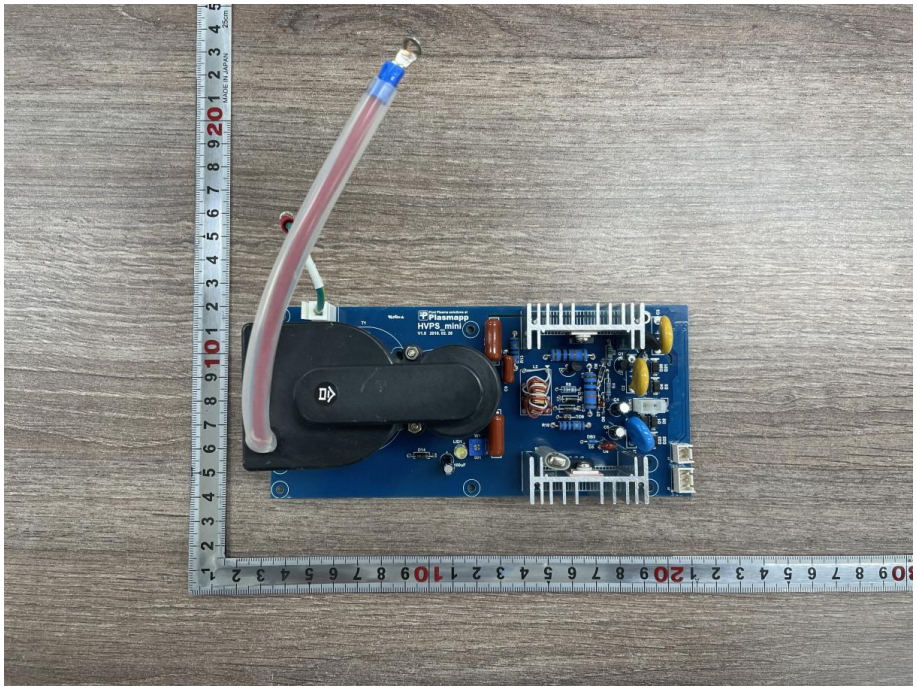


Attachment 1 - Photographs

<Rear side view Main control board>

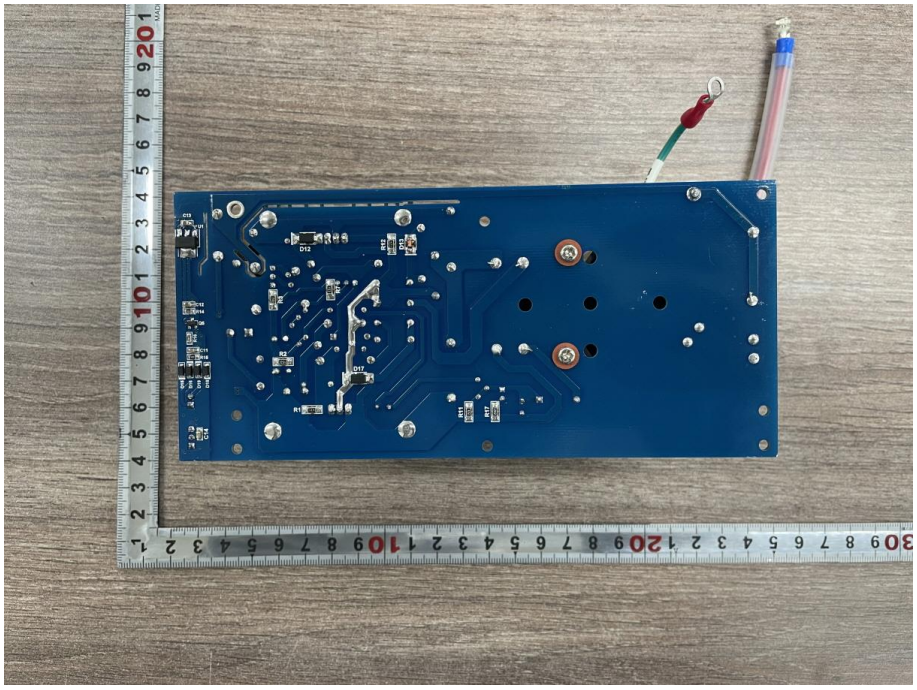


<Front side view High Voltage Transformer board>

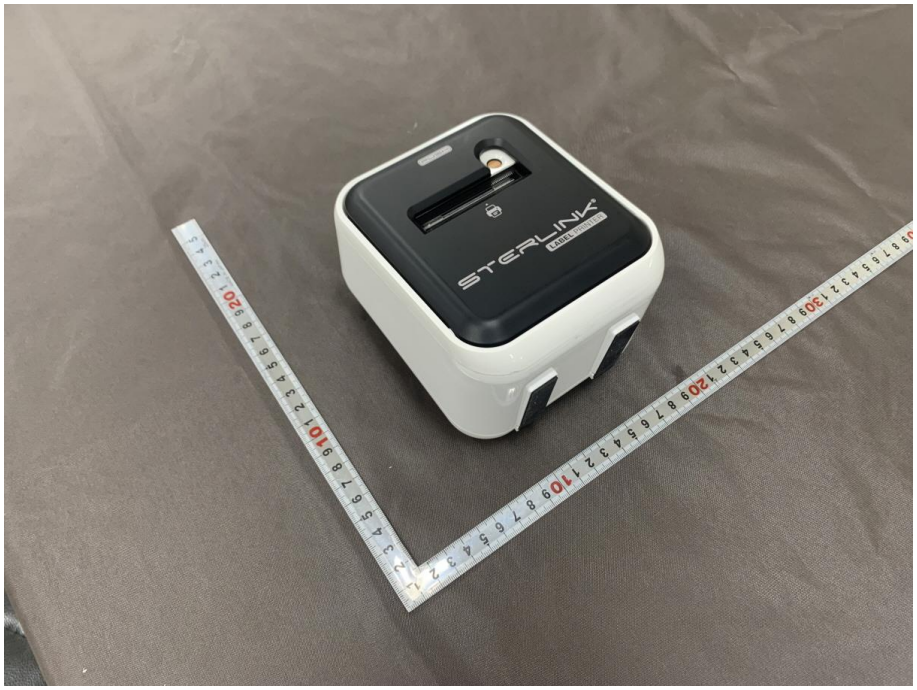


Attachment 1 - Photographs

<Rear side view High Voltage Transformer board>

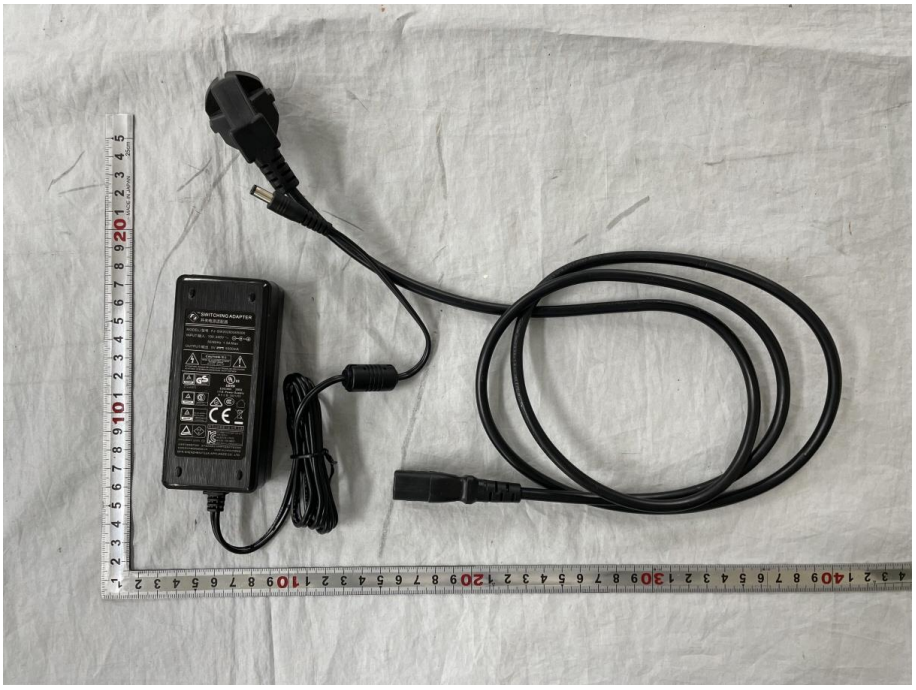


<Printer>

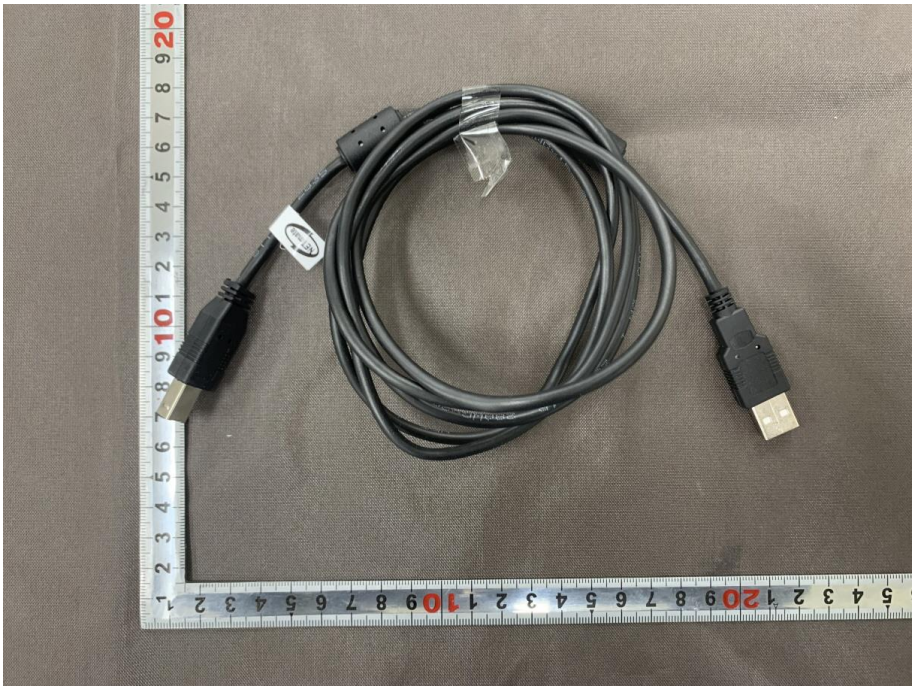


Attachment 1 - Photographs

<Printer AC/DC Adaptor>



<Connected Cable (Printer to Main unit)>



Attachment 1 - Photographs

<Power cord set>

Test Report issued under the responsibility of:
Dt&C Co., Ltd.

42, Yurim-ro, 154beon-gil, Cheoin-gu, Yongin-si,
Gyeonggi-do, 17042, Korea, Republic of

TEST REPORT

IEC 61010-2-040

Safety requirements for electrical equipment for measurement, control, and laboratory use Part 2-040 Particular requirements for sterilizers and washer-disinfectors used to treat medical materials

Report Number. ..... :	DRMKCEL2303-0016 Attachment A
Date of issue ..... :	2023-03-08
Total number of pages ..... :	32 pages
Name of Testing Laboratory preparing the Report ..... :	Dt&C Co., Ltd. 42, Yurim-ro, 154beon-gil, Cheoin-gu, Yongin-si, Gyeonggi-do, 17042, Korea, Republic of
Applicant's name ..... :	Plasmapp Co., Ltd.
Address ..... :	102, Cheombok-ro, Dong-gu, Daegu, 41061, Republic of Korea
Test specification:	
Standard ..... :	IEC 61010-2-040:2020 for use in conjunction with IEC 61010-1:2010/AMD1:2016
Test procedure ..... :	—
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	IEC61010_2_040C(Dt&C Co., Ltd.: TRF-MS-321(01)230203)
Test Report Form(s) Originator .... :	VDE Testing and Certification Institute (Dt&C modified on 2023-02-03)
Master TRF ..... :	2020-07-09

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.
This test report is related to KS Q ISO/IEC 17025 and KOLAS accreditation

General disclaimer:

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

If this test report is required to confirmation of authenticity, please contact to report@dtnc.net.

Test item description ..... :	Low temperature plasma sterilizer
Trade Mark ..... :	plasmapp
Manufacturer ..... :	Plasmapp Co., Ltd. 102, Cheombok-ro, Dong-gu, Daegu, 41061, Republic of Korea
Model/Type reference ..... :	STERLINK mini
Ratings ..... :	(220-240) V~, (50/60) Hz, 1.5 kVA

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):

☒	**Testing Laboratory:**	Dt&C Co., Ltd.	
Testing location/ address.....:		42, Yurim-ro, 154beon-gil, Cheoin-gu, Yongin-si, Gyeonggi-do, 17042, Korea, Republic of	
Tested by (name, function, signature).....:		(See IEC 61010-1 Test report)	
Approved by (name, function, signature)...:		(See IEC 61010-1 Test report)	
☐	**Testing procedure: CTF Stage 1 ..... :**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 2:**		
Testing location/ address.....:			
Tested by (name + signature) .....:			
Witnessed by (name, function, signature)..:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 3:**		
☐	**Testing procedure: CTF Stage 4:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Witnessed by (name, function, signature)..:			
Approved by (name, function, signature)...:			
Supervised by (name, function, signature) :			

List of Attachments (including a total number of pages in each attachment):
N/A

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
- Failure, or partial failure, of the mains supply (Clause 4.4.2.102)	☒ Permanent Testing Lab ☐ On Site Testing Dt&C Co., Ltd. (Satellite facilities-1) 46, Yurim-ro, 154beon-gil, Cheoin-gu, Yongin-si, Gyeonggi-do, 17042, Korea, Republic of

Summary of compliance with National Differences (List of countries addressed):
N/A

☐ **The product fulfils the requirements of _____ (insert standard number and edition and delete the text in parenthesis or delete the whole sentence if not applicable)**

Statement concerning the uncertainty of the measurement systems used for the tests
(may be required by the product standard or client)

☐ **Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:**

Procedure number, issue date and title:

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

☒ **Statement not required by the standard used for type testing**

(Note: When IEC or ISO standard requires a statement concerning the uncertainty of the measurement systems used for tests, this should be reported above. The informative text in parenthesis should be delete in both cases after selecting the applicable option)

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.

(See IEC 61010-1 Test report)

Test item particulars..... :	
Classification of installation and use..... :	(See IEC 61010-1 Test report)
Supply Connection ..... :	(See IEC 61010-1 Test report)
..... :	
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 IEC 61010-1 Test report)
Date (s) of performance of tests .....:	(See IEC 61010-1 Test report)

General remarks:

"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
“(See Form A.xx)” refers to a table at corresponding IEC 61010-1 Test Report
“(See Form B.xx)” refers to a table appended to this report.

The Test Results presented in this Test Report relate only to the objected tested. This Test Report shall not be reproduced except in full without the written approval of the testing laboratory.

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

Manufacturer’s Declaration per sub-clause 4.2.5 of IECEE 02:

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.

Name and address of factory (ies) ..... :	Plasmapp Co., Ltd. 102, Cheombok-ro, Dong-gu, Daegu, 41061, Republic of Korea

General product information:

(See IEC 61010-1 Test report)

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
4	**TESTS**		—
4.4	**Testing in SINGLE FAULT CONDITION**		P
4.4.2.5	Motors		N/A
	If impractical to test a motor when installed, separate identical motor tested at same conditions that exist inside the equipment.		N/A
4.4.2.13	Interlocks		N/A
	Tested without using toxic substances	No such part	N/A
4.4.2.101	Pressure controllers	No pressure controllers	N/A
	Pressure controllers overridden (except for overpressure protective devices complying with 11.7.4)		N/A
4.4.2.102	Failure, or partial failure, of the MAINS supply		P
	Following tests have been conducted:	(see Form B.1)	—
	Operate at 90 % of RATED voltage for one cycle		P
	Operate at 110 % of RATED voltage for one cycle		P
	Set to 90 % of RATED voltage for 5 min		P
	reduced (gradually 10 V / min) to.....:		P
	Reset to RATED voltage		P
4.4.2.103	Failure, or partial failure, of other supplies and services		N/A
	Each non-electrical and service supply interrupted or partial interrupted		N/A

5	**MARKING AND DOCUMENTATION**		—
5.1.2	Identification		P
	The equipment as a minimum marked with the following:		—
	a) name and address of the manufacturer	Manufacturer name marked	P
	b) additional markings required by national and local regulations		P
	name and address of the manufacturer's authorized representative		P
	c) equipment provides unique identifier (e.g. serial number)		P
	d) year and place of manufacturing; if different from manufacturer's address	One factory	N/A
	e) model identification	STERLINK mini	P
	f) designated purpose of the equipment.	Described on manual	P

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
5.1.101	Overpressure protective device	No overpressure safety device	N/A
	Identification includes:		—
	Name of manufacturer .....:		N/A
	Model number .....:		N/A
	If bursting disc marked with:		—
	Specified bursting pressure .....:		N/A
	Associate temperature .....:		N/A
5.1.102	PRESSURE VESSELS and shell boilers		N/A
	National and local regulations that may require additional markings considered		N/A
5.2	**Warning markings**		P
	Warning and caution symbols at least 10 mm high.		P
5.4.1	General		P
	Accompanying documents marked with:		—
	- Date of issue, or	Marked	P
	- Revision status and	Marked	P
	- Provided with the equipment		P
	If hazardous substances handled in NORMAL USE, the documentation includes:		—
	- information of constitutes, and		N/A
	- correct storage, and		N/A
	- correct use, and		N/A
	- safe disposal		N/A
	Marking, information and language:		—
	1) comply with regulations applying in the country of intended use	Described on manual	P
	2) incude instructions for the disposal of the equipment, its accessories and its packaging	Described on manual	P
	3) give due consideration to the technical knowledge, education and training of different OPERATOR categories	Described on manual	P
	4) not contradict information contained in documentation.	Not contradict	P
5.4.2	Equipement RATINGS		P
	aa) RATED ranges of pressure and flow rates for each non-electrical supply		P
5.4.3	Equipment installation		P
	Instructions including details for:		—

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	a) location and mounting	Described on manual	P
	b) space required for safe and efficient maintenance;	Described on manual	P
	c) individual weights of principal heavy subassemblies;	No heavy subassemblies	N/A
	d) overall weight and floor loading requirements;	Described on manual	P
	e) unpacking and assembly instructions (see als 7.108);	Described on manual	P
	f) MAINS supply requirements and connection		P
	temperature RATING of cable meet the requirements in 5.1.8;	Described on manual	P
	g) PERMANENTLY CONNECTED EQUIPMENT:		—
	1) supply wiring requirements;		N/A
	2) requirements for:		—
	- external switch or circuit-breaker (see 6.11.3.1)		N/A
	- external overcurrent protection devices (see 9.6.1)		N/A
	- recommendation for placement of switch or circuit breaker near to the equipment;		N/A
	h) ventilation requirements (see 11.101, 13.1.103.1, and 13.1.101)		N/A
	i) drainage requirements (see 11.101)	Described on manual	P
	j) instructions for protective earthing	Described on manual	P
	k) instructions related to sound level (see 12.5.1)	No sound power	N/A
	l) requirements for special services (air, feed water, cooling liquid, etc.)	No special services	N/A
	m) requirements related to hazardous gas atmospheres (see 13.0)	No hazardous gas atmospheres	N/A
	n) positioning of the equipment not difficult to operate disconnecting device	Described on manual	P
	o) Hazardous substances:	No hazardous substances	—
	- instructions for handling		N/A
	- instructions for containment		N/A
	- additional equipment is required for control of emissions (see 13.1)		N/A
	p) instructions relating to HAZARDS caused by:	No hazardous caused	—
	- liquids or		N/A
	- hot items falling from the equipment (see 9.1)		N/A

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	q) requirements for material used		—
	- in the installation of the equipment		P
	- which may come in contact with sterilant (see 13.1.103.4 and 13.2.101);		N/A
	r) instructions for ambient illumination (see 11.102);	Described on manual	P
	s) instructions relating to heat emission.		N/A
5.4.3.101	Special systems		P
	Installation instructions including details for:		—
	a) non-recirculating ventilation system for room (see 13.1.103.3)		N/A
	Ventilation systen give min. 10 air changes per hour .....:		N/A
	b) if toxic sterilant used:		—
	protection against HAZARDS arising from room ventilation failure (see 13.1.103.3)		N/A
	c) non-recirculating local exhaust system to remove fugitive emissions (see 13.1.101.4)		N/A
	d) drainage system (see 13.1.101.3)		N/A
	e) venting system for the drain (see 13.1.101.3)		N/A
	f) CHAMBER exhaust system (see 13.1.101.2)		N/A
	g) system to control escaping biological emissions (see 13.1.104)		N/A
	h) any other non-electrical supplies		P
	including prevention of back syphonage		P
5.4.4	Equipment operation		P
	a) identification of operating controls and	Described on manual	P
	their use in all operating modes;		P
	b) positioning for disconnection	Described on manual	P
	c) instructions for accessories and other equipment:		—
	including details for:		—
	interconnection		P
	suitable accessories		P
	detachable parts		P
	special materials		P
	d) specification of limits for intermittent operation	Continuous operation	N/A

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	e) an explanation of symbols related to safety which are used on the equipment (see 5.2)	Described on manual	P
	f) instructions for cleaning (see 11.2)	Described on manual	P
	g) instructions for making equipment safe after incomplete OPERATING CYCLE	Described on manual	P
	h) instructions for correct use of lockable door closure prevention device (see 7.102.b)	Described on manual	P
	i) instructions for safe access to LOAD in CHAMBER in case of failure addressed to RESPONSIBLE BODY (see 13.1.102)	Described on manual	P
	j) intruction for actions in case of a malfunction including fault diagnosis	Described on manual	P
	k) loading procedure	Described on manual	P
	l) instructions for safe disposal of parts as:		—
	detergent containers	No detergent containers	N/A
	sterilant containers	Described on manual	P
	parts contaminated by pathogenic material	No pathogenic material	N/A
	m) instructions for testing the function of critical safety devices (see 11.7.4)	No overpressure safety devices	N/A
	n) handling of substances involved in NORMAL USE:	No handling of substances involved	—
	correct use		N/A
	safety provisions		N/A
	methods of safe handling before disposal		N/A
	recommendations on disposal		N/A
	o) methods of reducing burn HAZARDS from surfaces permitted to exceed temperature limits	No such surfaces	N/A
	p) guidelines to follow in case of emergency in which eye, skin contact or inhalation could occur	Described on manual	P
	guidelines prominently displayed on or near the equipment		P
	q) instructions for safely replenishing containers for dosing chemicals (see 13.102)	No such containers	N/A
	r) appropriate warning stating types of LOAD which may be used	No hazard other than intended use	N/A
	s) consumable materials:	No such materials	—
	details of HAZARDS arising from introduction of incorrect quantities consumable materials		N/A

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	procedures and details of protection to minimise such HAZARDS		N/A
	t) identification of residual RISKS and instructions on necessary protective procedures (see clause 17)	No residual risks	N/A
5.4.5	Equipment maintenance and service		P
	Instructions provide sufficient details to:		—
	- permit safe maintenance and	Described on manual	P
	- inspection and testing	Described on manual	P
	- ensure continued safety of the equipment after the maintenance and inspection procedure		P
	Instructions include:		—
	a) details of maintenance on parts subjected to wear and tear if failure could lead to a HAZARD	Described on manual	P
	b) inspection and replacement of hoses and liquid containing parts if their failure could lead to a HAZARD	Described on manual	P
	c) safety devices fitted:	Described on manual	—
	settings and		P
	replacement procedures		P
	d) procedure for making the equipment safe prior to maintenance.	Described on manual	P
	e) maintenance schedules and repair procedures, including		N/A
	ambient lighting level (see 11.102) and		N/A
	special precautions to protect against HAZARDS during repair		N/A
	f) methods of safe handling and disposal for parts containing or contaminated by toxic and/or pathogenic material	No pathogenic material	N/A
	g) specific battery type for equipment using replaceable batteries	No battery	N/A
	h) RATINGS and characteristics of replaceable fuses	Described on manual	P
	i) a list of parts (if any):		—
	restricted to examination, and / or		N/A
	supplied by the manufacturer or manufacturer's agent		N/A
	j) residual RISKS (see clause 17) and	No residual risks	N/A
	protective measures for these RISKS		N/A

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	k) verification of the safe state after repair	Described on manual	P
5.4.101	OPERATOR training		P
5.4.101.1	General		P
	Instructions include statement for RESPONSIBLE BODY to ensure that OPERATORS are adequately trained:		—
	a) in operating or maintaining the equipment	Described on manual	P
	b) if exposure limits (i.e. STEL or LTEL) or	No toxic materials	N/A
	permissible working environmental concentration limits (see note to 13.1), could exceeded in NORMAL USE		N/A
	This instructions includes information about:		—
	- relevant health HAZARDS		N/A
	- national regulations		N/A
	- methods for safe use		N/A
	- leak detection methods		N/A
	c) regular training for all personnel concerned with operation or maintenance including:	Not necessary to requiar training	—
	Emergency procedures for any toxic, flammable, explosive or pathogenic material released into environment,		N/A
	attendance records maintained,		N/A
	evidence of understanding demonstrated		N/A
5.4.101.2	Procedures for potentially hazardous actions	Described on manual	P
	Safety procedures specified for any hazardous action to be carried out by OPERATOR		P
	Statement that RESPONSIBLE BODY must provide OPERATORS training in this procedures		P
6	**PROTECTION AGAINST ELECTRIC SHOCK**		—
6.2.2	Examination		N/A
	FIXED EQUIPMENT and equipment with a weight more than 80 kg:	41 kg (Main unit with Pump module)	—
	- not tilted or moved to check the bottom	(See above)	N/A
	- test finger applied in any part of the bottom can be reached		N/A
7	**PROTECTION AGAINST MECHANICAL HAZARDS AND AGAINST HAZARDS RELATED TO MECHANICAL FUNCTIONS**		—
7.1	**General**		P

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	Conformity is checked by 7.2 to 7.7 and 7.101 to 7.110		P
7.4	**Stability**		P
	aa) horizontal door supporting the LOAD withstand 1.2 times of the heaviest RATED LOAD	No damaged	P
7.5	**Provisions for lifting and carrying**		N/A
7.5.101	Transfer of LOADS into and out of the CHAMBER		N/A
	Means to protect OPERATOR against mechanical HAZARDS during transfer	No mechanical hazard	N/A
	Means provided to locate and retain the LOAD and its carrier in the correct position		N/A
	Means provided to prevent sliding shelf tilting or disengaging	No such part	N/A
	Force required for loading / unloading does not exceed 250 N	Max. 20 N	N/A
7.101	**Doors, conveyors, etc.**		P
	No HAZARD is caused in NORMAL CONDITION or SINGLE FAULT CONDITION by:		—
	a) mechanism to open, close or retain door		P
	b) wear on threaded parts	No such parts	N/A
	c) residual movement of:		N/A
	1) operation of emergency shut-down device	No shut-down device	N/A
	2) loss of power		N/A
	3) component failure		N/A
	4) removal of an obstruction		N/A
	d) parts driven by power or stored energy	No stored energy	N/A
7.102	**Access to the CHAMBER**		P
	Access not possible during OPERATING CYCLE if could cause to a HAZARD	Not possible	P
	Means provided to prevent:	No such chamber	—
	a) starting of the OPERATING CYCLE if OPERATOR is inside		N/A
	b) door closing (if fitted) if OPERATOR is inside		N/A
	The means are:		—
	- lockable by dedicated key or TOOL or other mechanism, and		N/A
	- manufacturer's instructions specify that the OPERATOR must retain the key or TOOL while inside the CHAMBER, and		N/A

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	- A warning marking (see 5.2) on the equipment clearly visible to the OPERATOR:	No such chamber	—
	- instruction for the OPERATOR to lock the means and		N/A
	- to retain the locking key, or TOOL at all times		N/A
	Hot liquid remaining in CHAMBER does not cause a hazard in NORMAL CONDITION or	No hot liquid	N/A
	- a warning is kept in manufacturer's instructions and		N/A
	- a warning marking provided (see 5.2)		N/A
	In SINGLE FAULT CONDITION no HAZARD caused by liquids and steam when the door is openend or at the attempt to open it	No liquids and steam	N/A
7.103	**Prevention of entry of gases, steam or liquids**		P
	Until the door is closed and secured, an Interlock is provided to:		—
	- prevent entering or generating of sterilant gas, carrier gas, steam or others in the CHAMBER and		P
	- all pressure retaining parts are engaged		N/A
7.104	**Prevention of new OPERATING CYCLE**		P
	Start of a new OPERATING CYCLE is not possible, if HAZARDS arising of a failure in:		—
	a) door operating system	New operating cycle is not possible	P
	b) LOAD transport system	No load transport system	N/A
	c) exhaust system	No exhaust system	N/A
	d) any other device (e. g. timer or sensor)	New operating cycle is not possible	P
	e) operation of the emergency shut-down device	No emergency shut-down device	N/A
7.105	**Pressure-retaining parts of a door**		P
	Interlock prevents release of door until CHAMBER is vented to atmospheric pressure		P
7.106	**Doors of equipment for use with fluids in containers**		N/A
	Door locked until:		—
	Temperature of the LOAD and fluid in the CHAMBER is below boiling point at ambient pressure	No such chamber	N/A
	Equipment designed to process fluids in sealed unvented containers:	No such chamber	—

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	- incorporate additional controls to keep door locked until the temperature of fluid inside the containers at athmospheric pressure has fallen to:		N/A
	- 20 K below boiling point of water for glass containers, or		N/A
	- 10 K below boiling point water for flexible containers		N/A
	Means provided to compensate the reduced boiling point at increased alstitude		N/A
	Temperature sensing of fluids never based on sensing a single container.		N/A
7.107	**Double-ended equipment**		N/A
	In NORMAL USE opening or closing of the door at remote end of CHAMBER not possible for the OPERATOR	No double-ended equipment	N/A
	Except for maintenance, opening of both doors at the same time is prevented		N/A
	Opening of the door at remote end not possible if the conditions inside the equipment could cause a HAZARD		N/A
7.108	**Transport and packaging**		N/A
	Packaging fitted with, or accept attachments for easily connection to standard lifting equipment	No such part	N/A
	Equipment and equipment parts packed in a manner that:		—
	- all parts of the equipment remain in position and stable, and		N/A
	- no HAZARD is caused		N/A
	Outside of the packaging marked with instructions for:		—
	- handling,		N/A
	- transport,		N/A
	- storage,		N/A
	- environment,		N/A
	- unpacking		N/A
7.109	**Guards and panelling**		N/A
	Removal or opening of a guard or panel require the use of a tool (see 14.102)	No guards and panelling	N/A
	If an access for persons is provided in a panel, this access:		—
	- not less than 500 mm wide and 1500 mm high,		N/A

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	- free from obstruction and		N/A
	- require the use of a TOOL.		N/A
	Fixings for attaching guards and panels are remain attached to either the guard, or panel, or to the structure of the equipment.		N/A
7.110	**Emergency shutdown device**		N/A
	Easily reached and prominently placed push button or other actuator	No emergency shut-down device	N/A
	The shutdown device is:		—
	a) not disconnect auxiliary circuits necessary for protection against HAZARD		N/A
	b) disconnect accessories necessary for the correct function of the equipment and		N/A
	which if disconnected separately could cause a HAZARD		N/A
	Installation instructions specify requirements for the interconnection of accessories necessary for the correct function of the equipment.		N/A
	If a mechanical HAZARD could occur, there must be an actuator:		—
	- placed within 1 m of the hazardous moving part		N/A
	- designed to withstand a force of 250 N sustained for a minimum period of 0.75 s		N/A
	Shutdown device operates automatically if power supply to any door or conveyor is interrupted.		N/A
	While emergency shutdown device is in operation:		—
	1) residual movement of powered part does not cause a HAZARD		N/A
	2) potentially hazardous parts returned to safe state		N/A
	parts included to control compressed air, steam, liquids and contaminated materials		N/A
	Interlock system prevents restoration of normal operation until hazardous conditions are eliminated		N/A
	Resetting the emergency shut-down device possible only with a key, code or other means or		N/A
9	**PROTECTION AGAINST THE SPREAD OF FIRE**		—
9.1	**General**		N/A
	If HAZARD caused by hot items fall from the equipment:		—

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	Equipment not to be placed on surfaces which could cause a fire or fume, therefore		N/A
	- Warning provided, and		N/A
	- included instruction manual		N/A
9.5	**Requirements for equipment containing or using flammable liquids**		N/A
9.5.101	Requirements for equipment containing or using flammable gases		N/A
	see 11.7.4. d), 11.104 g and 13.2.102	No flammable gases	N/A
10	**EQUIPMENT TEMPERATURE LIMITS AND RESISTANCE TO HEAT**		—
10.1	**Surface temperature limits for protection against burns**		N/A
	For hot items falling outfrom the equipment, see Clause 9.1	No hot items	N/A
	If easily touched heated surfaces are necessary for functional reasons:	No such surface	—
	- they are permitted to exceed the values of table 19 in NORMAL CONDITION and		N/A
	- to exceed 105°C in SINGLE FAULT CONDITION		N/A
	only if:		—
	- they are recognizable as such by appearance or function or		N/A
	- are marked with symbol 13 of Table 1 (see 5.2).		N/A
10.3	**Other temperature measurements**		N/A
	Additional temperatures are within the limits:		—
	aa) LOAD and fluid in the CHAMBER after a full OPERATING CYCLE, immediately before the door can be opened (in accordance with the requirement of 7.106)		N/A
	bb) Fluid in sealed unvented containers at the end of one OPERTING CYCLE (in accordance with the requirement 7.106)		N/A
	The temperature must be measured in NORMAL CONDITION and SINGLE FAULT CONDITION:		—
	cc) of the CHAMBER wall (10.5.101)		N/A
	dd) material (10.5.101)		N/A
	ee) of parts contacted by sterilant (13.2.102.2)		N/A
10.5	**Resistnce to heat**		N/A
10.5.101	Other materials		N/A

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	Tempertures of materials not result in deterioration of materials performance in NORMAL CONDITION and SINGLE FAULT CONDITION	No hazardous materials	N/A
11	**PROTECTION AGAINST HAZARDS FROM FLUIDS AND SOLID FOREIGN OBJECTS**		—
11.1	**General**		N/A
	Pathogenic substances (13.1.104)		N/A
	Chemical dosing (13.102)		N/A
11.7.2	Leakage and rupture at high pressure		N/A
	PRESSURE VESSELS and shell boilers meet the requirements of 14.101		N/A
11.7.4	Overpressure protective device	No overpressure safety device	N/A
	If maximum working pressure will exceeded, the:		—
	- Overpressure protection device fitted as specified in ISO 4126-1, and		N/A
	- set to operating pressure less than maximum working pressure, and		N/A
	- ensure that 110 % of maximum working pressure does not exceeded.		N/A
	An overpressure protective device is:		—
	- not operate in NORMAL USE, and		N/A
	- fulfill all of the following requirements:		—
	a) connected as close as possible to the parts to be protected		N/A
	b) installed in accordance to manufacturers instructions, and		N/A
	provide easy access for inspection, maintenance and repair		N/A
	c) adjustment possible only by the aid of a TOOL		N/A
	d) no HAZARD caused by location of discharge opening		N/A
	e) no shut-off valve located between overpressure protective device and parts to be protected		N/A
	f) fluid is unlikely to accumulate seat of valve		N/A
	g) drain connection located at lowest position not cause a HAZARD		N/A
	h) constructed of materials not be degraded in NORMAL USE that could cause a HAZARD		N/A

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	i) marked according 5.1.101		N/A
	Bursting disc only used in combination with overpressure protective device		N/A
	Bursting disc is conformed with ISO 4126-2		N/A
11.101	**Discharge to atmosphere**		P
	Discharge of pressure venting does not cause a HAZARD	No hazard	P
	Discharge pipe:	Not used	—
	- has a continous fall to its outlet; or		N/A
	- automatic drain provided at relevant locations; or		N/A
	- specified in manufacturer`s instructions (see also 11.7.4 g))		N/A
	Discharge released inside equipment:		—
	- no pressure built up during ventilation		P
	- no HAZARD occurs from venting or discharge		P
11.102	**Instruments and indicating devices**		N/A
	Indication provided if necessary to protect against a HAZARD	No such parts	N/A
	a) CHAMBER pressure		N/A
	b) jacket pressure		N/A
	c) OPERATING CYCLE counter		N/A
	d) current stage of the OPERATING CYCLE		N/A
	e) failure or partial falure of safety-related supplies		N/A
	f) line pressure for sterilant or chemical supply		N/A
	g) detection of leaks (see 13.1.103.1)		N/A
	h) water pump pressures		N/A
	i) vapor condenser temperature		N/A
	j) operating temperature		N/A
	Redundancy must be provided to assure that the OPERATOR receives sufficient information to avoid a HAZARD, even in SINGLE FAULT CONDITION		N/A
	During operation by a maintenance person		—
	- safety related devices easily seen by OPERATOR		N/A
	- Readable from 1 m distance		N/A
	- at illumination level in the range of (215 ± 15) lx to (1500 ± 15) lx.		N/A
11.103	**Protection of hot and cold water services**		N/A

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	Means provided conform with relevant requirements of IEC 61770		N/A
	National and local regulations considered.		N/A
	If provided by RESPONSIBLE BODY stated in instructions		N/A
11.104	**Equipment with inflatable or pressure activated seals**		N/A
	Means provided include the following:	No inflatable or pressure activated seals	—
	a) OPERATING CYCLE stops		N/A
	b) audible or visible alarm signal as fault indicator		N/A
	c) door remains closed		N/A
	d) supply of sterilant, disinfectant, steam, water or air into the CHAMBER interrupted		N/A
	e) local exhaust ventilation		N/A
	f) sterilant gas:		—
	source is isolated by automatic operated valve		N/A
	complete system evacuated to discharge pipe		N/A
	g) In case of flammable sterilant, complete system is purged with air or inert gas		N/A
12	**PROTECTION AGAINST RADIATION, INCLUDING LASER SOURCES, AND AGAINST SONIC AND ULTRASONIC PRESSURE**		—
12.5	**Sonic and ultrasonic pressure**		N/A
12.5.1	Sound level	No sound level	N/A
	no hazardous noise level produced, or		N/A
	maximum sound pressure level measured:		—
	- at OPERATOR'S position in NORMAL USE dB(A)		N/A
	- at a distance of 1 m from the ENCLOSURE dB(A)		N/A
	Exceptions:		—
	- sound from alarms		N/A
	- sound from parts remote from the equipment		N/A
	Hazardous sound pressure level described at the instructions.		N/A
	Installation instructions specify, how the RESPONSIBLE BODY can ensure that:		—
	- sound pressure level from equipment, will not reach a value that could cause a HAZARD after installation		N/A

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	1) Identify readily available and practicable protective materials or		N/A
	measures which may be used		N/A
	2) sound pressure level measured in NORMAL USE		N/A
	- at the OPERATOR'S position and		N/A
	- at a point 1m from the ENCLOSURE in a location that has the highest sound pressure level		N/A
13	**PROTECTION AGAINST LIBERATED GASES, SUBSTANCES, EXPLOSION AND IMPLOSION**		—
13.1	**Poisonous and injurinous gases and substances**		P
	RISK assessment carried out if leakage could cause a toxic or explosive atmosphere in NORMAL CONDITION and in SINGLE FAULT CONDITION.:	No poisonous and injurious gases	—
	For CHAMBER access during OPERATING CYCLE, see 7.102 a)		N/A
	For preventing the start of a new OPERATING CYCLE, see 7.104		N/A
	For fire HAZARD from hot items falling out of equipment, see clause 9 (3).		N/A
13.1.101	CHAMBER discharge systems		P
13.1.101.1	Discharge from the CHAMBER		P
	Does not cause a HAZARD		P
13.1.101.2	Failure of CHAMBER exhaust system		N/A
	If a HAZARD could arise:	No hazard	—
	- indicated by audible or visible alarm signals, independent from MAINS supply		N/A
	- emergency power system provided, if a failure in MAINS supply occure		N/A
	During a failure in CHAMBER exhaust system:		—
	- start of an OPERATING CYCLE prevented or		N/A
	- access to LOAD prevented		N/A
13.1.101.3	Protection from gases liberated from a drain		N/A
	Discharge from CHAMBER does not cause a HAZARD		N/A
	Installation instructions include statement for venting to a safe place		N/A
13.1.101.4	Local exhaust ventilation		N/A
	Means provided to connect to local exhaust system		N/A

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	Installation instructions must be warn the RESPONSIBLE BODY that:		—
	a) additional local exhaust ventilation may also be required in storage areas for sterilant gas;		N/A
	b) the discharge from a local exhaust ventilation system is located so as not to cause HAZARD.		N/A
13.1.102	LOAD access after fault		P
	Instructions for safe access to LOAD after a fault provided		P
13.1.103	HAZARDS arising from the use of toxic sterilant		N/A
13.1.103.1	CHAMBER leakage		N/A
	If a HAZARD could arise:		—
	OPERATING CYCLE includes leakage check before sterilant gas is admitted to CHAMBER		N/A
	Equipment reverted to safe condition in case of hazardous leakage		N/A
	Non-return valve provided to prevent the escape of toxic sterilant gas for equipment operating above atmospheric pressure		N/A
13.1.103.2	Protection against gases liberated from the LOAD		N/A
	Door locked until sterilant concentration is reduced to safe level for OPERATOR.....:		N/A
	Manufacturer must be advise the RESPONSIBLE BODY of any change required to take account of the very different gas absorption characteristics of materials processed.....:		N/A
13.1.103.3	Failure of room ventilation system		N/A
	If room ventilation is required to prevent a HAZARD:		—
	a) the equipment go into safe state		N/A
	b) start of a new OPERATING CYCLE is prevented		N/A
	c) indicated by both audible and visible alarm signal		N/A
13.1.103.4	Materials in contact with sterilant		N/A
	- not react with sterilant or carrier gas		N/A
	- not lead to a leakage in sufficient quantity		N/A
	Instructions include:		—
	- advise that the material used in the installation is not react with sterilant or carrier gas		N/A
13.1.104	Pathogenic substances		N/A

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	Emission of aerosols or fluids do not cause a HAZARD:		—
	- in NORMAL CONDITION, or		N/A
	- in SINGLE FAULT CONDITION.		N/A
	Installation instructions include:		—
	additional means required to control emissions		N/A
13.2	**Explosion and implosion**		N/A
13.2.101	Materials in contact with sterilant		N/A
	Materials in contact with sterilant not reacting with sterilant or carrier gas, causing:		—
	- change in pressure resulting in explosion or implosion		N/A
	Statement included in instructions		N/A
	Attention paid for selection of material:		—
	- for effects of galvanic attack		N/A
	- for different rates of expansion		N/A
	Alloy with more than 65 % mass fraction of copper not used		N/A
13.2.102	Explosion, implosion and fire of toxic gas STERILIZERS		N/A
13.2.102.1	Flammable sterilants		N/A
	Equipment using flammable sterilant, provide no source of ignition:		—
	- inside the CHAMBER,		N/A
	- inside its sterilant containers,		N/A
	- inside its exhaust pipings		N/A
	Protection in NORMAL and SINGLE FAULT CONDITION if mixture with air during process:		—
	Concentration reduced to below flammable limit before air is admitted at end of OPERATING CYCLE		N/A
	OPERATING CYCLE ensures prevents processing of next step of sterilization cycle in case of fire or explosion HAZARD		N/A
	CHAMBER exhaust system complies with 13.1.101.2		N/A
13.2.102.2	Heating of flammable liquid sterilant		N/A
	Steriliant containers not subjected to direct heating		N/A
	Flammable or explosive liquids not come into contact with electrical heating element		N/A
	Temperature of parts in contact with sterilant:		—

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	not cause fire or explosion HAZARD in NORMAL and SINGLE FAULT CONDITION		N/A
13.101	**Other HAZARDS araising from the use of toxic sterilants**		N/A
13.101.1	General		N/A
13.101.2	Opening or disconnecting a sterilant supply system		N/A
	Means provided to prevent HAZARDS (e. g. purging)		N/A
13.101.3	Gas blending		N/A
	No toxic, fire or explosion HAZARD occurs as result from incorrect mixing in NORMAL and SINGLE FAULT CONDITION		N/A
13.101.4	Sterilant supply		N/A
	Additional controls or mechanisms provided to interrupt sterilant supply to CHAMBER		N/A
	Means provided for safe dispensing, connecting and positioning of containers		N/A
13.101.5	Supply from sterilant cartridges		N/A
	Means prevent access during OPERATING CYCLE		N/A
13.101.6	Isolation of any part of sterilant supply system		N/A
	Overpressure protectivedevice complies 11.7.4		N/A
13.101.7	Failure of sterilant supply control system		N/A
	Indicated by visible alarm signal		N/A
	Equipment in safe state		N/A
	Initiating OPERATING CYCLE not possible		N/A
13.102	**Chemical dosing systems**		N/A
	Means provided to replenish containers without creating a HAZARD		N/A

14	**COMPONENTS AND SUBASSEMBLIES**		—
14.101	**PRESSURE VESSELS and shell boilers**		N/A
	Comply with applicable national PRESSURE VESSEL regulations, codes or standards.....:		N/A
	or		—
	meet the requirements of clause 11.7		N/A
14.102	**Access ports**		N/A
	If opened and closed by OPERATOR without the use of a TOOL:		—
	opening prevented, if HAZARD exists		N/A
14.103	**Control systems**		N/A

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	If OPERATOR setting causes a HAZARD, a warning marking is provided (see 5.2)	No such setting	N/A
	Automatic controller provided with system to control access to system functions		N/A
	The following functions are protected by increasingly severe constrains [examples in brackets]:		—
	a) initiating of OPERATING CYCLE [operator]		N/A
	b) selection of OPERATING CYCLE [OPERATOR / SUPERVISORS]		N/A
	c) changing OPERATING CYCLE parameters [supervisors]		N/A
	d) manual advance through OPERATING CYCLE [suitable trained technicians]		N/A
	e) maintenance [suitable trained technicians]		N/A
	f) changing OPERATING CYCLE programme [manufacturer or agent]		N/A
	Except for a) and b), above functions require the use of different keys, codes or other equivalent means.		N/A
	Higher-level TOOLS, keys or codes may allow access to lower levels.		N/A
	Termination of OPERATING CYCLE does not require special TOOL, key or code		N/A
	Disabling of safety devices prevented during NORMAL USE even in manual advance or automatic mode		N/A
	Selection of manual mode disables automatic controller		N/A
14.104	**Microprocessors**		N/A
	Failure of safety-related microprocessors does not cause a HAZARD		N/A
	Loss of processor memory battery power does not lead to a HAZARD	No such battery	N/A
14.105	**Asbestos**		N/A
	No parts of asbestos used	Not used	N/A
15	**PROTECTION BY INTERLOCKS**		—
15.1	**General**		N/A
	Interlock system fulfil the requiments of:	(Refer to IEC 61010-1 Test report)	—

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	IEC 62061 (SIL) or		N/A
	ISO 13849 (PL) or		N/A
	other solutions providing equivalent functional safety.		N/A

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict

4.4	**TABLE: Testing in single FAULT CONDITION – Results**			**Form B.1**	P
Test subclause	Fault No.	Fault description	Td 4.4.3 (NOTE)	How was test terminated Comments	Meets 4.4.4
4.4.2.102	1	Operate with 90 % of rated voltage	02:52:00	No adverse effects. No hazards	P
4.4.2.102	2	Operate with 110 % of rated voltage	01:38:00	No adverse effects. No hazards	P
4.4.2.102	3	Set to 90 % of RATED voltage for 5 min	00:05:00	No adverse effects. No hazards	P
4.4.2.102	4	reduced (gradually 10 V / min)	00:06:00	No adverse effects. No hazards (180 V~, Normal operation stop)	P

NOTE Td = Test duration in hh:mm:ss
Record temperature tests on Form B.4.
Record in the comments column for each test whether carried out during or after SINGLE FAULT CONDITION.

Supplementary information:

TESTED BY: MyeongSang You DATE: 2023-01-25 TEST EQUIPMENT LIST ITEM: M-S119, M-S126, M-S120, M-S124, M-S133

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict

7.5.101	**TABLE: Transfer of LOADS into and out of the CHAMBER**		**Form B.2**	N/A
Description where test applied		Force (N)	Remark	Verdict
Supplementary information:				

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

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict

7.101	**TABLE: Doors, conveyors etc.**			**Form B.3**	N/A
Description where test applied		Force (N)	Interlocked Yes / No	Remark	Verdict
Supplementary information:					

7.101 d)	**TABLE: Residual movement**		N/A
Description where test applied	Speed cm / s	Distance moved (cm)	Verdict
Supplementary information:			

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

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict

11.7.4	**TABLE: Overpressure protective device**			**Form B.4**	N/A
Part	Maximum permissible working pressure MPa	Pressure inside PRESSURE VESSEL MPa	Safety device operating YES / NO	Remark	
Supplementary information:					

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

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict

12.5.1	**TABLE: Sound level**		**Form B.5**	N/A
Locations tested		Measured maximum sound level dB(A)	Remarks / Comments	
At operator's normal position and at 1 m distance				
a)				
b)				
c)				
d)				
e)				
f)				
Supplementary information:				

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

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict

SP	**TABLE: Additional or special tests conducted**		N/A
Clause and Name of Test		Test type and condition	Observed results
Supplementary information:			

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

- The end -