

IEC 61010-2-040/ EN 60601-2-040 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 Reference No.	RL/2014/10004
Tested by	Koen Ke Test Engineer
Approved by	Porson Fu Assistant Manager
Date of issue	July 01 th , 2014
Total number of pages.....	29
Testing Laboratory	SGS Taiwan Ltd., Safety Laboratory
Address.....	134, Wu Kung Road, New Taipei Industrial Park, Wu Ku District, New Taipei City, Taiwan
Applicant's name.....	Sturdy Industrial Co., Ltd.
Address.....	168, Sec. 1, Zhongxing Road, Wugu District, New Taipei City 24872, Taiwan, R.O.C
Test specification:	
Standard	IEC 61010-2-040: 2005 (ed.1); EN 61010-2-040: 2006 for use in conjunction with IEC 61010-1:2001 (ed.2)
Test procedure	V.o.C Scheme
Non-standard test method.....	None
Test Report Form No.....	SGS_IEC61010_2_040A
Test Report Form(s) Originator.....	VDE Testing and Certification Institute
Master TRF	Dated 2006-06
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Test item description	Autoclaves
Trade Mark.....	Sturdy
Manufacturer	Sturdy Industrial Co., Ltd.
Model/Type reference.....	SAT-X1HPX2-X3-X4X5
Ratings.....	230V-440V 3~, 50/60Hz, 38kW max.

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List of Attachments (including a total number of pages in each attachment):
See IEC 61010-1 Test Report (report reference no. RL/2014/10048)

Summary of testing:

Tests performed (name of test and test clause):
See IEC 61010-1 Test Report
(report reference no. RL/2014/10048)

Testing location:
All tests as described within this
test report and as described in the
Measurement Section were
performed at the laboratory
described on cover page.

Details and test results are given in subsequent pages of this report.
This report refers only to the unit(s) submitted for test.

"(see Enclosure #)" refers to additional information appended to the report.

"(see appended table)" refers to a table appended to the report.

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Copy of marking plate:

See IEC 61010-1 Test Report (report reference no. RL/2014/10048).

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Test item particulars	
Type of item tested	Laboratory use equipment
Description of equipment function	Sterilizer
Installation/overvoltage category	III
Measurement category	None
Protection class	Class I (Permanent PE connected)
Pollution degree	2
Environmental rating	Standard
Equipment mobility	Fixed
Connection to mains supply	Permanent
Operating conditions	Continuous
Overall size of the equipment (W x D x H)	120 (W) x 220 (H) x 190 (D) cm
Mass of the equipment (kg)	865
Marked degree of protection to IEC 60529	None
Accessories and detachable parts included in the evaluation	None
Options	None
Possible test case verdicts:	
<ul style="list-style-type: none"> test case does not apply to the test object test object does meet the requirement test object does not meet the requirement 	
Testing	
Date of receipt of test item	Jan. 2 nd , 2014
Date (s) of performance of tests	Jan. 2 nd , 2014 - Apr. 28 th , 2014

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General remarks:

The test results presented in this report relate only to the object tested.
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"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
Throughout this report a comma (point) is used as the decimal separator.

This Test Report Form is intended for the investigation of testing and measurement circuits in accordance with IEC 61010-1:2010. It can only be used together with the Part 1 TRF for the appropriate edition of IEC 61010-1.

Manufacturer's Declaration per sub-clause 6.2.5 of IEC 61010-1:

The application for obtaining a Test Report 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

Name and address of factory (ies) Sturdy Industrial Co., Ltd.
168, Sec. 1, Zhongxing Road, Wugu District, New Taipei City 24872, Taiwan, R.O.C

General product information:

See IEC 61010-1 Test Report (report reference no. RL/2014/10048)

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	TABLE: 1 - Test Report Index Page	
Document No.	Documents included / attached to this report (description)	Page Numbers
TABLE 1	This page	Pass
TABLE 2	List of test equipment used for measurements	Pass
TABLE 3	List of safety relevant components	Pass

	TABLE: 2 - Test equipment list	Pass
This Table may be included in main test report or kept in file for review (report reference no. RL/2014/10048)		

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IEC 61010-2-040			
Clause	Requirement - Test	Result - Remark	Verdict
	TABLE: 3 - List of components and circuits relied on for safety	See IEC 61010-1 Test Report, table 14 (report reference no. RL/2014/10048)	Pass

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Clause	Requirement - Test	Result - Remark	Verdict

4.4	TESTING IN SINGLE FAULT CONDITION (SFC)		Pass
4.4.2.4	Motors		Pass
	if impractical to test in place, separate identical motor tested	(see general report)	Pass
4.4.2.10	Heating devices		Pass
	aa) loss of feed water simulated	(see Form B.1)	Pass
4.4.2.12	Interlocks		Pass
	tested without using toxic substances	(see general report)	Pass
4.4.2.101	Pressure controllers		Pass
	Pressure controllers overridden (except for overpressure safety devices complying with 11.7.4)	(see Form B.1)	Pass
4.4.2.102	Failure, or partial failure, of the MAINS supply		Pass
	Following tests have been conducted:	(see Form B.1)	—
	Operate with 90 % of RATED voltage		Pass
	Operate with 110 % of RATED voltage		Pass
	Set to 90 % of RATED voltage for 5 min		Pass
	reduced (gradually 10 V / min) to: 197V		Pass
	Reset to RATED voltage		Pass
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		Pass
5.1.101	Overpressure safety device		Pass
	Identification includes:		—

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Clause	Requirement - Test	Result - Remark	Verdict
	Name of manufacturer.....:	Hsing Lu Company Ltd.	Pass
	Model number.....:	TCL4010	Pass
	If bursting disc marked with:	No such parts	—
	Specified bursting pressure.....:		N/A
	Associate temperature.....:		N/A
5.2	Warning markings		Pass
	Types of LOAD which may be used see 5.4.4 r); or	See instruction manual section "Placement for items to be sterilized"	Pass
	if insuffcient space symbol 14 Table 1 used		N/A
	Instruct OPERATOR to retain locking key or TOOL all the times while in the chamber see 7.102 b)		N/A
	HAZARD could occur from hot liquid remaining in CHAMBER see 7.102 c)		N/A
	Setting of a control could cause a HAZARD see 14.103		N/A
	Warning not to place equipment on surfaces which could cause a fire or fume if hot items fall from equipment		N/A
5.4.1	General		Pass
	aa) PRESSURE VESSEL conformity declaration	See instruction manual section "Specifications"	Pass
	bb) Information on constituents of hazardous substances	No such parts	N/A
5.4.2	Equipement ratings		N/A
	aa) RATED ranges of pressure and flow rates for each non-electrical supply	No such parts	N/A
5.4.3	Equipment installation		Pass
	Instructions including details for:		—

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Clause	Requirement - Test	Result - Remark	Verdict
5.4.3 a)	Location and mounting	See instruction manual section "Installation"	Pass
	space for maintenance	See instruction manual section "Installation"	Pass
5.4.3 b)	Weights of heavy sub-assemblies		N/A
5.4.3 c)	Overall weights and floor loading requirements	See instruction manual section "Specifications"	Pass
5.4.3 d)	Assembly	See instruction manual section "Specifications"	Pass
5.4.3 e)	Mains supply:	See instruction manual section "Specifications"	Pass
	Requirements	See instruction manual section "Specifications"	Pass
	connections		Pass
	Temperature RATING of cable		N/A
5.4.3 f)	Permanently connected equipment:		Pass
	Requirements for:		—
	external switch or circuit breaker		N/A
	recommendation for placement of switch or circuit breaker near to the equipment	See instruction manual section "Specifications"	Pass
	external overcurrent protection		N/A
5.4.3 g)	Ventilation and drainage requirements		N/A
5.4.3 h)	Protective earthing	See instruction manual section "Installation"	Pass
5.4.3 i)	Sound power data and requirements		N/A
5.4.3 j)	Requirements for special services (air, cooling liquid etc.)		N/A
5.4.3 k)	Requirements related to hazardous gas atmospheres		N/A

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Clause	Requirement - Test	Result - Remark	Verdict
5.4.3 l)	Positioning of the equipment not difficult to operate disconnecting device	See instruction manual section "Installation"	Pass
5.4.3 m)	Hazardous substances:	No such parts	N/A
	- handling		N/A
	- containment		N/A
	additional equipment is required for control of emissions		N/A
5.4.3 n)	Warning against HAZARDS may be caused by hot items	See instruction manual section "Important safety instructions"	Pass
5.4.3 o)	Requirements for materials which may get in contact with sterilant		N/A
5.4.3.101	Special systems	No such parts	N/A
	Installation instructions including details for:		—
5.4.3.101a)	Non-recirculating exhaust system for room		N/A
5.4.3.101b)	If toxic sterilant used:		N/A
	Protection against HAZARDS arising from room ventilation failure		N/A
5.4.3.101c)	Non-recirculating local exhaust system to remove fugitive emissions		N/A
5.4.3.101d)	Drainage system		N/A
5.4.3.101e)	Venting system for the drain		N/A
5.4.3.101f)	CHAMBER exhaust system		N/A
5.4.3.101g)	System to control escaping biological emissions		N/A
5.4.3.101h)	Any other non-electrical supplies		N/A
	including prevention of back syphonage		N/A
5.4.4	Equipment operation		Pass
	Instructions include in detail:		—

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	A statement about protection impairment if used in a manner not specified by the manufacturer	See instruction manual section "Important safety instructions"	Pass
5.4.4 a)	Operating controls including	See instruction manual section "Operation"	Pass
	identification		Pass
	use in all operating modes		Pass
5.4.4 b)	Positioning for disconnection		Pass
5.4.4 c)	Accessories and other equipment:	No such parts	N/A
	including details for:		—
	interconnection		N/A
	suitable accessories		N/A
	detachable parts		N/A
	special materials		N/A
5.4.4 d)	Limits for intermittent operation	No such parts	N/A
5.4.4 e)	Explanation of required and used symbols	See instruction manual section "Explanation of safety symbols and notes"	Pass
5.4.4 f)	Cleaning	Refer to instruction manual section "Maintenance instructions"	Pass
5.4.4 g)	Measures to make equipment safe after incomplete OPERATION CYCLE	See instruction manual section "Troubleshooting"	Pass
5.4.4 h)	Use of lockable door closure prevention device	See instruction manual section "Important safety instructions"	Pass
5.4.4 i)	Safe access to LOAD in CHAMBER in case of failure addressed to RESPONSIBLE BODY	See instruction manual section "Important safety instructions"	Pass
5.4.4 j)	Actions in case of a malfunction including fault analysis	See instruction manual section "Troubleshooting"	Pass
5.4.4 k)	Loading procedure	See instruction manual section "Placement for items to be sterilized"	Pass

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Clause	Requirement - Test	Result - Remark	Verdict
5.4.4 l)	Safe disposal of parts as:	No such parts	N/A
	detergent containers		N/A
	sterilant containers		N/A
	parts contaminated by pathogenic material		N/A
5.4.4 m)	Testing the function of critical safety devices		N/A
5.4.4 n)	Handling of substances involved in NORMAL USE:	See instruction manual section "Important safety instructions"	Pass
	correct use		Pass
	safety provisions		Pass
	methods of safe handling before disposal	No such parts	N/A
	recommendations on disposal		Pass
5.4.4 o)	Methods of reducing burn HAZARDS from surfaces permitted to exceed temperature limits	See instruction manual section "Important safety instructions"	Pass
5.4.4 p)	Guidelines in case of emergency in which eye, skin contact or inhalation could occur		N/A
5.4.4 q)	Safely replenishing containers for dosing chemicals		N/A
5.4.4 r)	Appropriate warning stating types of LOAD which may be used		N/A
5.4.4 s)	Consumable materials:	No such parts	N/A
	details of HAZARDS arising from introduction of incorrect quantities consumable materials		N/A
	procedures and details of protection to minimise such HAZARDS		N/A
5.4.5	Equipment maintenance		Pass
	Instructions specifies nature and frequency of:		—
	- inspections	See instruction manual section "Maintenance instructions"	Pass
	- test	See instruction manual section "Operation"	Pass

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	- preventive maintenance	See instruction manual section "Maintenance instructions"	Pass
	Details of parts likely to be replaced	See instruction manual section "Maintenance instructions"	Pass
	Specification of parts only to be examined or supplied by the manufacturer or his agent		Pass
	Instructions include:		—
5.4.5 a)	Details of maintenance for parts which could lead to a HAZARD in case of failure	See instruction manual section "Maintenance instructions"	Pass
5.4.5 b)	Inspection and replacement of hoses and liquid containing parts		N/A
5.4.5 c)	Safety devices fitted:		N/A
	settings		N/A
	replacement procedures		N/A
5.4.5 d)	Making equipment safe prior to maintenance		Pass
5.4.5 e)	Maintenance schedules and repair procedures	See instruction manual section "Maintenance instructions"	Pass
	Special precautions against HAZARDS during repair		Pass
5.4.5 f)	Methods of safe handling for		Pass
	parts contaminated by pathogenic material		N/A
	detergent containers		N/A
	and others		N/A
	Recommendation on disposal procedures	See instruction manual section "Important safety instructions"	Pass
5.4.5 g)	Specific battery type of user replaceable batteries		N/A
5.4.5 h)	RATING and characteristics of replaceable fuses		N/A
5.4.101	OPERATOR training		N/A
5.4.101.1	Instructions include statement for RESPONSIBLE BODY to ensure that OPERATORS are adequately trained:		N/A
5.4.101.1a)	all personnel operating or maintaining the equipment is trained in operation and safe use		N/A
5.4.101.1b)	Comprehensive instructions for personnel working with toxic materials	No such parts	N/A

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Clause	Requirement - Test	Result - Remark	Verdict

	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
5.4.101.1c)	Regular training for all personnel concerned including:		N/A
	Emergency procedures for any toxic, flammable, explosive or pathogenic material released into environment		N/A
	Attendance records maintained		N/A
	Evidence of understanding		N/A
5.4.101.2	Procedures for potentially hazardous actions		N/A
	Safety procedures specified for any hazardous action to be carried out by operator		N/A
	Statement that RESPONSIBLE BODY must provide OPERATORS training in this procedures		N/A

6	PROTECTION AGAINST ELECTRIC SHOCK		Pass
6.1.1	Requirements		Pass
	For electrical requirements clause 13.0 is concerned if hazardous gas atmosphere can be created by using flammable or explosive sterilant	No such parts	N/A
6.2	Determination of ACCESSIBLE parts		Pass
6.2.1	Fixed equipment more than 80 kg not tilted or moved for examination but gaps evaluated		N/A
6.10.2	Fitting of non-detachable MAINS supply cords	No such parts	N/A
	aa) means for cord anchorage not used to attach any other components		N/A
6.101	Failure, or partial failure, of the MAINS supply		Pass
	Interruption of MAINS supply does not cause HAZARD (see 4.4.2.102)	(see Form B.1)	Pass

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Clause	Requirement - Test	Result - Remark	Verdict
	electrical safety system disabled		Pass
	non-electrical safety system disabled		N/A

7	PROTECTION AGAINST MECHANICAL HAZARDS		Pass
7.1	General		Pass
	Conformity is checked by 7.2 to 7.107		Pass
7.1.101	Emergency shut-down device	Located in front enclosure and see relevant photos in general report for details.	Pass
	operated by easily reached and prominently placed push button or other actuator		Pass
	Shutdown device does not disconnect auxiliary circuits necessary for protection against HAZARDS		Pass
	Actuator placed within 1 m of the hazardous moving part if mechanical HAZARDS could occur		Pass
	Shutdown device operates if power supply to any door or conveyor is interrupted		Pass
	While emergency shutdown device is in operation:		Pass
7.1.101 a)	residual movement of powered part does not cause a HAZARD	All movement of powered parts are enclosure within the metal enclosure.	Pass
7.1.101 b)	potentially hazardous parts returned to safe status		Pass
	parts included to control compressed air, steam, liquids and contaminated materials		N/A
	Resetting the emergency shut-down device with a key, code or other means or		N/A
	interlock system prevents restoration of normal operation until hazardous conditions are eliminated		Pass
7.2	Moving parts		Pass
	Exception for easily touched moving parts deleted		Pass

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Clause	Requirement - Test	Result - Remark	Verdict
7.3	Stability		Pass
	aa) Horizontal door supporting the LOAD withstand 120 % of the RATED LOAD		Pass
7.4	Provisions for lifting and carrying	No such parts	N/A
	Handles or grips withstand four times mass		N/A
7.4.101	Transfer of LOADS into and out of the equipment		Pass
	Means to protect OPERATOR against mechanical hazard during transfer		Pass
	Means to locate and retain the LOAD and its carrier in the correct position	See manual instruction section "Placement for items to be sterilized"	Pass
	Means to prevent sliding shelf tilting or disengaging		N/A
	Force required for loading / unloading does not exceed 250 N	(see Form B.2)	Pass
7.101	Doors, conveyors etc.		Pass
	No hazard is caused in NORMAL or SINGLE FAULT CONDITION by:		Pass
7.101 a)	mechanism to open, close or retain door		Pass
7.101 b)	wear on threaded parts	No such parts	N/A
7.101 c)	residual movement of:	No such parts	N/A
	i) operation of operation shut-down device		N/A
	ii) loss of power		N/A
	iii) component failure		N/A
	iv) removal of an obstruction		N/A
7.101 d)	parts power or driven by stored energy		N/A
7.102	Access to the CHAMBER		Pass
7.102 a)	OPERATOR access not possible during OPERATION CYCLE	An interlock protective device to lock the door for not accessible during operation cycle.	Pass

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Clause	Requirement - Test	Result - Remark	Verdict
7.102 b)	Means provided to prevent (while operator inside):	No such parts	N/A
	i) inadvertent operation		N/A
	ii) door closing		N/A
	Means locked by key or TOOL or other mechanism (see 5.2 and 5.4.4 h))		N/A
7.102 c)	Hot liquid remaining in CHAMBER does not cause a hazard in NORMAL CONDITION or	No such parts	N/A
	warning marking provided (see 5.2)		N/A
	No HAZARD from liquids occurs in SINGLE FAULT CONDITION during door opening		N/A
7.103	Prevention of entry of gas, etc.		Pass
	Interlock provided to prevent entering or generating of sterilant gas, carrier gas, steam or others in the CHAMBER until door locked and secured		Pass
7.104	Prevention of new OPERATING CYCLE		Pass
	Not possible to start new OPERATING CYCLE if hazard arising from following failures:		—
7.104 a)	door operating system	An interlock protective device to lock the door for new operating cycle starting	Pass
7.104 b)	LOAD transport system		N/A
7.104 c)	exhaust system		N/A
7.104 d)	any other device (e. g. timer or sensor)		N/A
7.105	Pressure-retaining parts of a door	Maximum internal pressure is 2.5 kg/cm ²	Pass
	Interlock prevents release of door until chamber is vented to atmospheric pressure		Pass
7.106	Doors of equipment for use with fluids in containers	No such parts.	N/A
7.106 a)	Door locked until temperature of LOAD and fluid in the CHAMBER is below boiling point at ambient pressure		N/A

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Clause	Requirement - Test	Result - Remark	Verdict
7.106 b)	For equipments processing fluids in sealed unvented containers		N/A
	additional controls provided to keep door locked until safe value for temperature of containers:		N/A
	- 20 K below boiling point of water for glass		N/A
	- 10 K below boiling point water for flexible		N/A
7.107	Double-ended equipment		Pass
	No possibility for OPERATOR to open or close door at remote end of CHAMBER	No such parts	Pass

9	PROTECTION AGAINST THE SPREAD OF FIRE		Pass
	If hot items fall from the equipment:		—
	Equipment not to be placed on surfaces which could cause a fire or fume, therefore		Pass
	- Warning provided, and		Pass
	- included instruction manual	See instruction manuals section "Important Safety Instructions"	Pass
9.4.101	Requirements for equipment containing or using flammable gases	No such parts	N/A
	see 11.7.4. d), 11.105 g), 13.2.102.1 to 13.101.6		N/A

10	EQUIPMENT TEMPERATURE LIMITS AND RESISTANCE TO HEAT		Pass
10.1	Surface temperature limits for protection against burns	(see Form B.4)	Pass
	For hot items fall from the equipment (see Clause 9)		Pass
10.3	Other temperature measurements	(see Form B.4)	Pass
	Additional temperatures are within the limits:		Pass
	In NORMAL CONDITION:		Pass

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Clause	Requirement - Test	Result - Remark	Verdict
10.3 aa)	LOAD and fluid in the CHAMBER (7.106 a))		Pass
10.3 bb)	Fluid in sealed unvented containers (7.106 b))	No such parts	N/A
	In NORMAL CONDITION and SINGLE FAULT CONDITION:		N/A
10.3 cc)	Chamber wall (10.5.101)		Pass
10.3 dd)	Material (10.5.101)		Pass
10.3 ee)	Parts contacted by sterilant (13.2.102)		N/A
10.5.101	Other materials	(see Form B.4)	Pass
	Tempertures of materials not result in deterioration of materials performance in NORMAL CONDITION and SINGLE FAULT CONDITION		Pass

11.	PROTECTION AGAINST HAZARDS FROM FLUIDS		Pass
11.1	General		Pass
	Pathogenic substances (13.104)	No such parts	N/A
	Chemical dosing (13.102)		N/A
11.4	Overflow		Pass
	Container overflow during refilling does not cause a HAZARD in NORMAL CONDITION		Pass
11.7.2	Leakage and rupture at high pressure		Pass
	Pressure vessels meet the requirements of 14.101		Pass
11.7.4	Overpressure safety device	Hopeet Enterprise Co., Ltd. S10	Pass
	Overpressure safety device fitted, and		Pass
	set to operating pressure less than maximum working pressure		Pass
	Pressure not exceeding 110 % of maximum working pressure	(see Form B.5)	Pass
	Not operating in NORMAL CONDITION, and		Pass

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	operates to following requirements:		—
11.7.4 a)	Connected close as possible to parts to be protected		Pass
11.7.4 b)	Installed in accordance to valve manufacturers instruction		Pass
	Easy access for inspection, maintenance and repair		Pass
11.7.4 c)	Adjusted only by use of a TOOL		N/A
11.7.4 d)	Location of discharge opening		Pass
11.7.4 e)	No shut-off valve located between overpressure safety device and parts to be protected		N/A
11.7.4 f)	Fluid is unlikely to accumulate seat of valve		Pass
11.7.4 g)	Drain connection located at lowest position	No such parts	N/A
11.7.4 h)	Constructed of materials not be degraded to cause a hazard		Pass
11.7.4 i)	Device in the scope of 4126-1 is conform with its requirements		N/A
11.7.4	Bursting disc only used in combination with overpressure safety device	No such parts	N/A
	Bursting disc is conform with ISO 6718		N/A
11.101	Discharge to atmosphere		Pass
	Discharge of pressure venting does not cause a HAZARD		Pass
	Discharge pipe:		—
	- has a continuous fall to its outlet; or		Pass
	- automatic drain provided at relevant locations; or		N/A
	- specified in manufacturer's instructions		N/A
	Discharge released inside equipment:		—
	- no pressure built up during ventilation		Pass

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IEC 61010-2-040			
Clause	Requirement - Test	Result - Remark	Verdict
	- No HAZARD occurs from venting or discharge		Pass
11.102	Instruments and indicating devices		—
	Indication provided if necessary for safety:		Pass
11.102 a)	CHAMBER pressure		Pass
11.102 b)	Jacket pressure		Pass
11.102 c)	OPERATING CYCLE counter		Pass
11.102 d)	Current stage of the OPERATING CYCLE		Pass
11.102 e)	Failure of safety-related supplies		Pass
11.102 f)	Line pressure for sterilant or chemical supply	No such parts of sterilant or chemical supply	Pass
11.102 g)	Detection of leaks		Pass
11.102 h)	Water pump pressures	Maximum internal pressure is 2.5 kg/cm ²	Pass
11.102 i)	vapor condenser temperature		Pass
11.102 j)	Operating temperature		Pass
11.102	Correct indication in SINGLE FAULT CONDITION		Pass
	- safety related devices easily seen by OPERATOR		Pass
	- Readable from 1 m distance	199 lx	Pass
11.103	Failure, or partial failure, of non-electrical supplies and services		Pass
	Failure does not cause a HAZARD		Pass
11.104	Protection of hot and cold water services	No such parts	N/A
	Means provided conform with relevant requirements of IEC 61170		N/A
	If provided by RESPONSIBLE BODY stated in instructions		N/A
11.105	Equipment with inflatable or pressure activated seals	No such parts	—

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Clause	Requirement - Test	Result - Remark	Verdict

	Means provided include the following:		N/A
11.105 a)	OPERATING CYCLE stops		N/A
11.105 b)	audible or visible alarm signal as fault indicator		N/A
11.105 c)	door remains closed		N/A
11.105 d)	supply of steam, water or air into the CHAMBER interrupted		N/A
11.105 e)	local exhaust ventilation		N/A
11.105 f)	Sterilant gas:	No such parts	N/A
	Source is isolated by automatic operated valve		N/A
	Complete system evacuated to discharge pipe		N/A
11.105 g)	In case of flammable sterilant complete system is purged with air or inert gas	No such parts	N/A

13	PROTECTION AGAINST LIBERATED GASES, PATHOGENIC SUBSTANCES, EXPLOSION AND IMPLOSION		Pass
13.0	General		N/A
	Risk assessment carried out to determine HAZARDS from leakage of highly toxic, flammable or explosive chemicals		N/A
	In case of doubt IEC 60079 considered		N/A
13.1	Poisonous and injurious gases	No such parts	N/A
	Dangerous amounts of such gases not liberated in NORMAL and SINGLE FAULT CONDITION		N/A
13.1.101	CHAMBER discharge systems		Pass
13.1.101.1	Discharge from the CHAMBER		Pass
	Does not cause a HAZARD		Pass
13.1.101.2	Failure of CHAMBER exhaust system	No such parts	N/A
	indicated by audible or visible alarm signal		N/A

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Clause	Requirement - Test	Result - Remark	Verdict
	- Alarm signal independent from MAINS SUPPLY		N/A
	Starting of OPERATING CYCLE not possible		N/A
	ACCESS to load prevented		N/A
13.1.101.3	Protection from gases liberated from a drain	Steam was discharged into water storage tank of equipment, no hazard	Pass
	Discharge from CHAMBER does not cause a HAZARD		Pass
	Installation instructions include statement for venting to a safe place		N/A
13.1.101.4	Local exhaust ventilation	No such parts	N/A
	Means provided to connect to local exhaust system		N/A
13.1.102	LOAD access after fault		Pass
	Instructions for safe access to load after a fault provided		Pass
13.1.103	HAZARDS arising from the use of toxic sterilant		N/A
13.1.103.1	CHAMBER leakage		N/A
a)	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
b)	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	No such parts	N/A
	Door locked until sterilant concentration is reduced to safe level for OPERATOR		N/A
13.1.103.3	Failure of room ventilation system	No such parts	N/A
	Room ventilation required to prevent a HAZARD in NORMAL OR SINGLE FAULT CONDITION		N/A
	Measures provided including following:		—

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Clause	Requirement - Test	Result - Remark	Verdict
a)	Equipment in safe state		N/A
b)	Starting of new OPERATING CYCLE not possible		N/A
c)	Indicated by both audible and visible alarm signal		N/A
13.1.103.4	Materials in contact with sterilant	No such parts	N/A
	Materials in contact with sterilant not reacting with sterilant or carrier gas resulting:		N/A
	in material deterioration does not cause leakage		N/A
	Statement included in instructions		N/A
13.1.104	Pathogenic substances	No such parts	N/A
	Emission of aerosols or fluids do not cause a HAZARD		N/A
	If additional means required to control emissions those are specified in installation instructions		N/A
13.2	Explosion and implosion		N/A
13.2.101	Materials in contact with sterilant	No such parts	N/A
	Materials in contact with sterilant not reacting with sterilant or carrier gas with:		N/A
	change of pressure also by ignition or exothermic reaction		N/A
	Statement included in instructions		N/A
13.2.102	Explosion, implosion and fire of toxic gas STERILIZERS	No such parts	N/A
13.2.102.1	Flammable sterilants	No such parts	N/A
a)	No source of ignition within CHAMBER, its connections or exhaust piping		N/A
	Protection in NORMAL and SINGLE FAULT CONDITION if mixture with air during process:		N/A
	Concentration reduced to below flammable limit before air is admitted at end of OPERATING CYCLE		N/A

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Clause	Requirement - Test	Result - Remark	Verdict
	OPERATING CYCLE ensures prevents processing of next step of sterilization cycle in case of fire or explosion HAZARD		N/A
b)	CHAMBER exhaust system complies with 13.1.101.2	No such parts	N/A
13.2.102.2	Heating of flammable liquid sterilant	No such parts	N/A
	Sterilant containers not subjected to direct heating		N/A
	Flammable or explosive liquids not in direct contact with electrical heating element		N/A
	Temperature of parts in contact with sterilant:		—
	not cause fire or explosion HAZARD in NORMAL and SINGLE FAULT CONDITION		N/A
13.101	Other hazards arising from the use of toxic sterilants	No such parts	N/A
	Note: A toxic hazard is considered to occur if STEL or LTEL of the sterilant emission is exceeded		N/A
13.101.1	Opening or disconnecting a sterilant supply system	No such parts	N/A
	Means provided to prevent HAZARDS (e. g. purging)		N/A
13.101.2	Gas blending	No such parts	N/A
	No toxic, fire or explosion HAZARD occurs as result from incorrect mixing in NORMAL and SINGLE FAULT CONDITION		N/A
13.101.3	Sterilant supply	No such parts	N/A
	Additional controls or mechanisms are provided to interrupt sterilant supply to CHAMBER		N/A
	Means provided for safe dispensing, connecting and positioning of containers		N/A
13.101.4	Supply from sterilant cartridges	No such parts	N/A
	Means prevent access during OPERATING CYCLE		N/A
13.101.5	Isolation of any part of sterilant supply system	No such parts	N/A
	Overpressure safety device complies 11.7.4		N/A

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Clause	Requirement - Test	Result - Remark	Verdict
13.101.6	Failure of sterilant supply control system	No such parts	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	No such parts	N/A
	Means provided to replenish containers without creating a HAZARD		N/A

14	COMPONENTS		Pass
14.2.1	Motor temperatures	(see Form B.4)	Pass
	No hazard occurs through:		—
	current drawn by a motor when stopped		Pass
	loss of one supply phase of a three-phase motor		N/A
14.101	PRESSURE VESSELS	Refer to certificate no. 4028-2013-CE-RGC-ACCREDIA for details	Pass
	Comply with applicable national PRESSURE VESSEL regulations and codes for the country of intended use		Pass
14.102	Access ports	An interlock protective device to lock the door for not accessible.	Pass
	If opened and closed by OPERATOR without the use of a TOOL:		—
	Means provided to prevent opening		Pass
14.103	Control systems		Pass
	If OPERATOR setting causes a HAZARD, a warning marking is provided (see 5.2)		Pass
	Automatic controller provided with system to control access to system functions		Pass

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Clause	Requirement - Test	Result - Remark	Verdict
	The following functions are protected by increasingly severe constraints [examples in brackets]:		Pass
14.103 a)	Initiating of operating cycle [operator]		Pass
14.103 b)	Selection of operating cycle [operator / supervisors]		Pass
14.103 c)	Changing operating cycle parameters [supervisors]		Pass
14.103 d)	Manual advance through operating cycle [suitable trained technicians]		Pass
14.103 e)	Maintenance [suitable trained technicians]		Pass
14.103 f)	changing OPERATING CYCLE programme [manufacturer or agent]		Pass
	Termination of OPERATING CYCLE does not require special TOOL, key or code		Pass
	Disabling of safety devices prevented during NORMAL USE even in manual advance or automatic mode		Pass
	Selection of manual mode disables automatic controller		Pass
14.104	Microprocessors		Pass
	Failure of safety-related microprocessors does not cause a hazard		Pass
	Loss of processor memory battery power does not lead to a hazard		Pass
14.105	Asbestos	No such parts	Pass
	No parts of asbestos used		Pass

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IEC 61010-2-040					
Clause	Requirement - Test			Result - Remark	Verdict
4.4	TABLE: Testing in single FAULT CONDITION – Results			Form B.1	Pass
Test subclause	Fault No.	Fault description	Td 4.4.3 (NOTE)	How was test terminated Comments	Meets 4.4.4
4.4.2	1	Loss of feed water	06h:07m	No breakdown, No hazardous. Unit displayed error message after loss of feed water. Input: 0.08 A. Max.temp:72.1°C for door cover; Ambient: 23.5°C	Pass
4.4.2	2	Failure of the mains supply	10h:26m	No breakdown, No hazardous. 197V is the breaking voltage after failure of the mains supply. Input: 78.3 A. Max.temp:74.6°C for door cover; Ambient: 26.9°C	Pass
NOTE Td = Test duration in h:min:s 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:					

TRF No. IEC61010_2_040A

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Clause	Requirement - Test	Result - Remark	Verdict

7.4.101	TABLE: Transfer of LOADS into and out of the CHAMBER		Form B.2	Pass
Description where test applied		Force N	Remark	Verdict
Push the load into the chamber		31.0	Not over than 250 N	Pass
Pull the load from the chamber		23.0	Not over than 250 N	Pass
Supplementary information:				

7.101 c)	TABLE: Doors, conveyors etc.	Form B.3	N/A
7.101 d)	TABLE: Residual movement		N/A

10.	TABLE : Temperature Measurements	Form B.4A	Pass
Refer to Report No. RL/2014/10047, sub-clause 10 Temperature test for details.			

10.2	TABLE: Temperature of windings Resistance method Temperature Measurements	Form B.4B	N/A
-------------	--	------------------	-----

11.7.4	TABLE: Overpressure safety device			Form B.5	Pass
Part		Maximum permissible working pressure MPa	Pressure inside PRESSURE VESSEL MPa	Safety device operating YES / NO	Remark
Metal pressure valve (S10)		0.255 (2.6 kgf/cm ²)	0.392 (4.0 kgf/cm ²)	Yes	
Pressure protective device (TCL4010)		0.255 (2.5 kgf/cm ²)	0.441 (4.5 kgf/cm ²)	Yes	
Pressure protective device (TCL4013)		0.245 (2.5 kgf/cm ²)	0.441 (4.5 kgf/cm ²)	Yes	
Supplementary information:					

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