TEST REPORT

IEC 61010-2-040 / EN 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. ..... :	UT106078-2
Compiled by (+ signature) ..... :	Tony Cheng / Vice Manager
Approved by (+ signature)..... :	Steven Chang / Assistant GM
Date of Issue ..... :	January 23, 2018
Total number of pages ..... :	32 pages
Applicant's name..... :	Sturdy Industrial Co., Ltd.
Address ..... :	No. 168, Sec. 1, Zhongxing Rd., Wugu District, New Taipei City 24872, Taiwan
Test specification:	
Standard ..... :	IEC 61010-2-040: 2015, EN 61010-2-040: 2015 for use in conjunction with IEC 61010-1:2010 & EN61010-1:2010
Test procedure..... :	According to above
Non-standard test method..... :	N/A
Testing laboratory name..... :	Universal Testing Inc.
	(TAF Certification No. 1994)
Address.....:	2F, No. 13, Lane 28, Sec.1, Huanshan Road, Nei-Hu, Taipei 114, Taiwan
Testing location .....:	as above
Test item description……..:	Autoclave Sterilizer
Trade Mark……..:	STURDY
Manufacturer ……:	Same as the applicant
Model/Type reference……...:	SA-252F , SA-300H, SA-302H, SA-300VF,SA-300VL, SA-300VLA
Ratings……..:	220 – 240 V , 50 / 60 Hz, 9A (SA-252F) , 11.9 A (SA-300H,SA-302H) ,13.5 A (SA-300VF), 10A (SA-300VL, SA-300VLA)

List of Attachments (including a total number of pages in each attachment):
None

Summary of testing: passed

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, leave it blank or delete the whole sentence, if not applicable)**

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/ EN 61010-1 report

Test item particulars ..... :	
Classification of installation and use ..... :	Laboratory Use Equipment
Supply Connection ..... :	Cord connected
..... :	
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 ..... :	November 15, 2017
Date (s) of performance of tests ..... :	December 25 , 2017 – January 22, 2018

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.

Name and address of factory (ies) ..... : Same as the applicant

General product information:

It is a Class I equipment with metal enclosure. It incorporates a pressure vessel using steam and intended for the treatment of medical materials and for laboratory processes. It is without automatic loading and unloading system. For indoor use only. All models are completely the same except the heater , size of the chamber and the enclosure. Tests were done with Model SA-252F and SA-300VLA as the representative except where noted.

This report must be used with the IEC 61010-1 (EN 61010-1) basic standard report No. UT106078-1 .

IEC/ EN 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
4	**TESTS**		P
4.4	Testing in SINGLE FAULT CONDITION		P
4.4.2.5	Motors		N/A
	if impractical to test in place, separate identical motor tested	No motor used	N/A
4.4.2.13	Interlocks		P
	tested without using toxic substances	(see Form A.1)	P
4.4.2.101	Pressure controllers		P
	Pressure controllers overridden (except for overpressure safety devices complying with 11.7.4)	(see Form A.1)	P
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 cyle		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	Back to normal working conditon	P
4.4.2.103	Failure, or partial failure, of other supplies and services		P
	Each non-electrical and service supply interrupted or partial interrupted	(see Form B.1)	P

5	**MARKING AND DOCUMENTATION**		P
5.1.2	Identification		P
	The equipment marked with at least the following:		—
	a) name and address of the manufacturer		P
	b) additional markings required by national and local regulations		N/A
	name and address of the manufacturer's authorized representative		P
	c) equipment provide unique identifier (e.g. serial number)		P
	d) year and place of manufacturing; if different from manufacturer's address		N/A
	e) model identification		P

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Clause	Requirement - Test	Result - Remark	Verdict
	f) designated purpose of the equipment.		P
5.1.101	Overpressure safety device		P
	Identification includes:	Identification marked	—
	Name of manufacturer .....:		P
	Model number .....:		P
	If bursting disc marked with:		—
	Specified bursting pressure .....:	No such parts	N/A
	Associate temperature .....:	No such parts	N/A
5.1.102	PRESSURE VESSELS and shell boilers		N/A
	national and local regulations that may require additional markings considered	To be checked separately	N/A
5.2	Warning markings		P
	Warning markings specified in 5.1.5.1, 5.1.5.2 c), 5.1.5.2 d), 5.1.8, 5.4.4 r), 6.1.2 b), 7.3.2, 7.102 b), 7.102 c), 9.1, 10.1, 13.2.2, and 14.103		—
	meet the following requirements:		—
	Warning and Caution symbols at least 10mm high.		P
5.4.1	General		P
	Accompanying documents shall be marked with:		—
	- Date of issue, or		P
	- Revision status and		P
	- Provided with the equipment		P
	aa) national and local regulations apply to the documentation	To be checked separately	N/A
	bb) 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		N/A
	NOTE 2: ISO15223-2 offers guidance for equipment classified as a medical device.		—

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Clause	Requirement - Test	Result - Remark	Verdict
	2) incude instructions for the disposal of the equipment, its accessories and its packaging		P
	3) give due consideration to the technical knowledge, education and training of different OPERATOR categories	Considered appropriate	P
	4) not contradict information contained in documentation.	No contradict information	P
5.4.2	Equipement ratings		P
	aa) RATED ranges of pressure and flow rates for each non-electrical supply	No such supply	N/A
5.4.3	Equipment installation		P
	Instructions including details for:		—
	a) location and mounting		P
	b) space required for safe and efficient maintenance;		P
	c) individual weights of principal heavy subassemblies;	No subassemblies	N/A
	d) overall weight and floor loading requirements;		P
	e) unpacking and assembly instructions (see als 7.108)		P
	f) MAINS supply requirements		P
	connection		P
	temperature RATING of cable		N/A
	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)		P
	i) drainage requirements (see 11.101)		P
	j) protective earthing		P
	k) sound level (see 12.5.1)		N/A

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Clause	Requirement - Test	Result - Remark	Verdict
	l) requirements for special services (air, feed water, cooling liquid, etc.)		P
	m) requirements related to hazardous gas atmospheres (see 13.0)		N/A
	n) positioning of the equipment not difficult to operate disconnecting device		P
	o) Hazardous substances:		—
	- handling		N/A
	- containment		N/A
	- additional equipment is required for control of emissions (see 13.1)		N/A
	p) HAZARDS caused by:		—
	- liquids or		P
	- hot items falling from the equipment (see 9.1)		P
	q) requirements for material used		P
	- in the installation of the equipment		P
	- which may come in contact with sterilant (see 13.1.103.4 and 13.2.101)		P
	r) instructions for ambient illumination (see 11.102)	No such concern	N/A
	NOTE Guidance on lighting is offered in ISO12100-2 and EN1837		—
	s) instructions relating to heat emission		P
5.4.3.101	Special systems		N/A
	Installation instructions including details for:		—
	a) non-recirculating ventilation system for room (see 13.1.103.3)		N/A
	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

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Clause	Requirement - Test	Result - Remark	Verdict
	g) system to control escaping biological emissions (see 13.1.104)		N/A
	h) any other non-electrical supplies		N/A
	including prevention of back syphonage		N/A
5.4.4	Equipment operation		P
	a) identification of operating controls and		P
	their use in all operating modes;		P
	b) positioning for disconnection		P
	c) accessories and other equipment:		—
	including details for:		—
	interconnection		N/A
	suitable accessories		N/A
	detachable parts		N/A
	special materials		N/A
	d) specification of limits for intermittent operation		N/A
	e) an explanation of symbols related to safety which are used on the equipment (see 5.2)		P
	f) instructions for cleaning (see 11.2)		P
	g) measures to make equipment safe after incomplete OPERATION CYCLE		P
	h) use of lockable door closure prevention device (see 7.102.b)		N/A
	i) safe access to LOAD in CHAMBER in case of failure addressed to RESPONSIBLE BODY (see 13.1.102)		P
	j) actions in case of a malfunction including fault diagnosis		P
	k) loading procedure		P
	l) safe disposal of parts as:		—
	detergent containers		N/A
	sterilant containers		N/A
	parts contaminated by pathogenic material		P
	m) testing the function of critical safety devices (see 11.7.4)		N/A
	n) handling of substances involved in NORMAL USE:		—
	correct use		N/A

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Clause	Requirement - Test	Result - Remark	Verdict
	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		N/A
	p) guidelines to follow in case of emergency in which eye, skin contact or inhalation could occur		N/A
	guidelines prominently displayed on or near the equipment		N/A
	q) Safely replenishing containers for dosing chemicals (see 13.102)		N/A
	r) Appropriate warning stating types of LOAD which may be used		N/A
	s) Consumable materials:		—
	details of HAZARDS arising from introduction of incorrect quantities consumable materials		N/A
	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)		N/A
5.4.5	Equipment maintenance and service		P
	Instructions provide sufficient details to:		—
	- permit safe maintenance and		P
	- inspection and		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		P
	b) inspection and replacement of hoses and liquid containing parts if their failure could lead to a HAZARD		N/A
	c) safety devices fitted:		—
	settings and		N/A
	replacement procedures		N/A

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Clause	Requirement - Test	Result - Remark	Verdict
	d) procedure for making the equipment safe prior to maintenance.		P
	e) maintenance schedules and repair procedures, including		P
	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		N/A
	g) specific battery type for equipment using replaceable batteries		N/A
	h) RATING and characteristics of replaceable fuses		N/A
	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		N/A
	protective measures for these RISKS		N/A
	k) Verification of the safe state after repair		N/A
5.4.101	OPERATOR training		P
5.4.101.1	Instructions include statement for RESPONSIBLE BODY to ensure that OPERATORS are adequately trained:		—
	a) in operating or maintaining the equipment		P
	b) if exposure limits (i.e. STEL or LTEL) or		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	To be checked separately	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:		—
	Emergency procedures for any toxic, flammable, explosive or pathogenic material released into environment,		N/A

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Clause	Requirement - Test	Result - Remark	Verdict
	attendance records maintained,		N/A
	evidence of understanding demonstrated		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**		N/A
6.2.2	Examination		N/A
	FIXED EQUIPMENT and equipment with a weight more than 80 kg:	All less than 80 kg	—
	- not tilted or moved to check the bottom		N/A
	- test finger applied in any part of the bottom can be reached		N/A
7	**Protection against mechanical HAZARDS and against HAZARD related to mechanical functions**		P
7.1	General		P
	Conformity is checked by 7.2 to 7.107		P
7.4	Stability		N/A
	aa) Horizontal door supporting the LOAD withstand 1.2 times of the heaviest RATED LOAD		N/A
7.5.101	Transfer of LOADS into and out of the CHAMBER		P
	means to protect OPERATOR against mechanical hazard during transfer		P
	means to locate and retain the LOAD and its carrier in the correct position		N/A
	means to prevent sliding shelf tilting or disengaging		P
	force required for loading / unloading does not exceed 250 N	(see Form B.2)	P
7.101	Doors, conveyors, etc.		P
	No hazard is caused in NORMAL or SINGLE FAULT CONDITION by:		—
	a) mechanism to open, close or retain door		P
	b) wear on threaded parts	No such parts	N/A

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Clause	Requirement - Test	Result - Remark	Verdict
	c) residual movement of:	No movement may occur(see Form B.3)	P
	1) operation of emergency shut-down device		P
	2) loss of power		P
	3) component failure		P
	4) removal of an obstruction		P
	d) parts driven by power or stored energy	(see Form B.3)	N/A
7.102	Access to the CHAMBER		N/A
	Access not possible during OPERATION CYCLE if could cause to a HAZARD		N/A
	Means provided to prevent:		—
	a) starting of the operation cycle if OPERATOR is inside	Not for operator to enter inside	N/A
	b) door closing (if fitted) if OPERATOR is inside		N/A
	The means shall be:		—
	- lockable by dedicated key or TOOL or other mechanism, and		N/A
	- manufacturer's instructions shall specify that the OPERATOR must retain the key or TOOL while inside the CHAMBER, and		N/A
	- A warning marking (see 5.2) on the equipment clearly visible to the OPERATOR:		—
	- 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		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	Door is not possible to open in single fault condition or with manual force	P
7.103	Prevention of entry of gas, etc.		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		P

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Clause	Requirement - Test	Result - Remark	Verdict
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		P
	b) LOAD transport system		N/A
	c) exhaust system		P
	d) any other device (e. g. timer or sensor)		P
	e) operation of the emergency shut-down device		P
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		P
	Door locked until:	(see Form A.26A)	—
	temperature of the LOAD and fluid in the CHAMBER is below boiling point at ambient pressure		P
	Equipment designed to process fluids in sealed unvented containers:		—
	- 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	(see Form A.26A)	N/A
	- 10 K below boiling point water for flexible containers	(see Form A.26A)	N/A
	Means provided to compensate the reduced boiling point at increased altitude	Units used under 2000m	P
	Temperature sensing of fluids never based on sensing a single container.	Checked by single fault of temperature sensor	P
7.107	Double-ended equipment	Single end equipment	N/A
	In NORMAL USE opening or closing of the door at remote end of CHAMBER not possible for the OPERATOR		N/A
	Except for maintenance, opening of both doors at 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	No movement by hand	N/A

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Clause	Requirement - Test	Result - Remark	Verdict
	Packaging fitted with, or accept attachments for easily connection to standard lifting equipment		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)		N/A
	If a personal access is provided in a panel, this access:		—
	- not less than 500 mm wide and 1500 mm high,		N/A
	- free from obstruction and		N/A
	- require the use of a TOOL.		N/A
	Fixings for attaching guards and panels shall remain attached to either the guard, or panel, or to the structure of the equipment.		N/A
7.110	Emergency shut-down device		P
	operated by easily reached and prominently placed push button or other actuator	On front control panel	P
	The shutdown device:		—
	a) not disconnect auxiliary circuits necessary for protection against HAZARD		P
	b) disconnect accessories necessary for the correct function of the equipment and	No accessories	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

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Clause	Requirement - Test	Result - Remark	Verdict
	If a mechanical HAZARD could occur, there shall 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	All units stop operation	P
	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	Need manual reset	P
9	**PROTECTION AGAINST THE SPREAD OF FIRE**		P
	If hot items fall from the equipment:		—
	Equipment not to be placed on surfaces which could cause a fire or fume, therefore		P
	- Warning provided, and		P
	- included instruction manual		P
9.5.101	Requirements for equipment containing or using flammable gases		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**		P
10.1	Surface temperature limits for protection against burns		P
	For hot items falling outfrom the equipment, see Clause 9.1		P
	If easily touched heated surfaces are necessary for functional reasons:	(see Form A.26A)	—
	- they are permitted to exceed the values of table 19 in NORMAL CONDITION and		—
	- to exceed 105°C in SINGLE FAULT CONDITION		—

IEC/ EN 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	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).	Warning symbol marked	P
10.3	Other temperature measurements		P
	Additional temperatures are within the limits:	See report of the general standard	—
	In NORMAL CONDITION:	(see Form A.26A)	—
	aa) LOAD and fluid in the CHAMBER (7.106 a))	By the temperature sensor	P
	bb) Fluid in sealed unvented containers (7.106 b))	By the temperature sensor	P
	In NORMAL CONDITION and SINGLE FAULT CONDITION:	(see Form A.26A)	—
	cc) CHAMBER wall (10.5.101)		N/A
	dd) material (10.5.101)		N/A
	ee) Parts contacted by sterilant (13.2.102.2)		N/A
10.5.101	Other materials		N/A
	Tempertures of materials not result in deterioration of materials performance in NORMAL CONDITION and SINGLE FAULT CONDITION	(see Form A.26A)	N/A
11	**PROTECTION AGAINST HAZARDS FROM FLUIDS**		P
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		P
	PRESSURE VESSELS and shell boilers meet the requirements of 14.101		P
11.7.4	Overpressure safety device	(see Form B.4)	P
	If maximum working pressure will exceeded, the:		—
	- Overpressure safety device fitted as specified in ISO 4126-1, and shall	Pressure sensor and pressure controller were used	N/A
	- set to operating pressure less than maximum working pressure, and shall		P
	- ensure that 110 % of maximum working pressure does not exceeded.		P
	The overpressure safety device shall:		—
	- not operate in NORMAL CONDITION, and		N/A

IEC/ EN 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	- fullfill the following requirements:		—
	a) connected as close as possible to the parts to be protected	Connect with pipe system	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) Location of discharge opening		N/A
	e) no shut-off valve located between overpressure safety 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		N/A
	not cause a HAZARD		N/A
	h) Constructed of materials not be degraded to cause a HAZARD		N/A
	i) Marked according 5.1.101		N/A
	Bursting disc only used in combination with overpressure safety device		N/A
	Bursting disc is conform with ISO 4126-2		N/A
11.101	Discharge to atmosphere		P
	Discharge of pressure venting does not cause a HAZARD		P
	Discharge pipe:		P
	- has a continous fall to its outlet; or		P
	- 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:		N/A
	- no pressure built up during ventilation		P
	- no HAZARD occurs from venting or discharge		P
11.102	Instruments and indicating devices		P
	Indication provided if necessary to protect against a hazard		P
	a) CHAMBER pressure		P
	b) Jacket pressure		N/A

IEC/ EN 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
	c) OPERATING CYCLE counter		P
	d) current stage of the OPERATING CYCLE		P
	e) failure or partial falure of safety-related supplies		N/A
	f) line pressure for sterilant or chemical supply		P
	g) detection of leaks (see 13.1.103.1 a))		N/A
	h) water pump pressures		P
	i) vapor condenser temperature		N/A
	j) operating temperature		P
	Redundancy shall be provided to assure that the OPERATOR receives sufficient information to avoid a HAZARD, even in SINGLE FAULT CONDITION		P
	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 lx (± 15 lx) to 1500 lx (± 15 lx).		N/A
11.103	Protection of hot and cold water services		N/A
	Means provided conform with relevant requirements of IEC 61770	(see Attachment)	N/A
	National and local regulations considered.		N/A
	If provided by RESPONSIBLE BODY stated in instructions		N/A
11.105	Equipment with inflatable or pressure activated seals	Door Gasket	P
	Means provided include the following:		—
	a) OPERATING CYCLE stops		N/A
	b) audible or visible alarm signal as fault indicator		N/A
	c) door remains closed	For door seal	P
	d) supply of sterilant, disinfectant, steam, water or air into the CHAMBER interrupted		N/A
	e) local exhaust ventilation		N/A
	f) Sterilant gas:		N/A
	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

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Clause	Requirement - Test	Result - Remark	Verdict
12	**Protection against radiation, including laser sources, and against sonic and ultrasonic pressure**		N/A
12.3	Optical radiation		N/A
	unintentional escape of radiation at equipment provided with lamp or lamp systems emitting:		—
	ultraviolet radiation, or		N/A
	visible radiation, or		N/A
	infrared radiation, including light emitting diodes		N/A
	except for sources according Table 101……:	No such part	—
	assessed according IEC 62471, Risk Group……:	(see Attachment)	—
	labelled according IEC TR 62471-2	(see Photo Documentation)	N/A
	Accompanying documents contain:		—
	- protective measures,		N/A
	- restrictions on use		N/A
	- conditions of use of Table 102.		N/A
12.5	Sonic and ultrasonic pressure		P
12.5.1	Sound level		—
	no hazardous noise level produced, or		P
	maximum sound pressure level measured		—
	- at operator's position in NORMAL USE dB(A)……:	(see Form B.5) no such part	N/A
	- at a distance of 1 m from the ENCLOSURE dB(A)….:	(see Form B.5) no such part	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
	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

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Clause	Requirement - Test	Result - Remark	Verdict
	- 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**		N/A
13.1	Poisonous and injurinous gases and substances		N/A
	Dangerous amounts of such gases not liberated in NORMAL and SINGLE FAULT CONDITION	No gases or substances may liberate	N/A
	If potentially-hazardous substances are liberated, the OPERATOR shall not be exposed to a quantity of the substance that could cause harm		N/A
	Discharge is not considered to be liberation of hazardous substances		N/A
	Risk assessment carried out if leakage could cause a toxic or explosive atmosphere in NORMAL CONDITION and in SINGLE FAULT CONDITION.:		—
	For CHAMBER access during OPERATING CYCLE, see 7.102 a)		—
	For preventing the start of a new OPERATING CYCLE, see 7.104		—
	For fire HAZARD from hot items falling out of equipment, see clause 9 (3).		—
13.1.101	CHAMBER discharge systems		N/A
13.1.101.1	Discharge from the CHAMBER		N/A
	Does not cause a HAZARD		N/A
13.1.101.2	Failure of CHAMBER exhaust system		N/A
	If a HAZARD could arise:		—
	- 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

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Clause	Requirement - Test	Result - Remark	Verdict
	Installation instructions include statement for venting to a safe place		N/A
13.1.101.4	Local exhaust ventilation	Not used	N/A
	Means provided to connect to local exhaust system		N/A
	Installation instructions shall 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 a HAZARD.		N/A
13.1.102	LOAD access after fault		N/A
	Instructions for safe access to load after a fault provided		N/A
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 shall 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	No such conditions	N/A
	Materials in contact with sterilant:		—

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Clause	Requirement - Test	Result - Remark	Verdict
	- 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 must not react with sterilant and carrier gas		N/A
13.1.104	Pathogenic substances		N/A
	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	Sterilant not used	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	Not used	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

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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
	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 in direct contact with electrical heating element		N/A
	Temperature of parts in contact with sterilant:	(see Form A.26A)	—
	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	Opening or disconnecting a sterilant supply system		N/A
	Means provided to prevent HAZARDS (e. g. purging)		N/A
13.101.2	Gas blending		N/A
	No toxic, fire or explosion HAZARD occurs as result from incorrect mixing in NORMAL and SINGLE FAULT CONDITION	(see Form B.1)	N/A
13.101.3	Sterilant supply	Not used	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
13.101.4	Supply from sterilant cartridges		N/A
	Means prevent access during OPERATING CYCLE		N/A
13.101.5	Isolation of any part of sterilant supply system		N/A
	Overpressure safety device complies 11.7.4		N/A
13.101.6	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**	P

IEC/ EN 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
14.101	PRESSURE VESSELS and shell boilers		P
	Comply with applicable national PRESSURE VESSEL regulations, codes or standards……..:	To be checked separately	N/A
	or		—
	meet the requirements of clause 11.7	Checked with pipe system	P
14.102	Access ports	No such construction	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
	If OPERATOR setting causes a HAZARD, a warning marking is provided (see 5.2)		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

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Clause	Requirement - Test	Result - Remark	Verdict
	Failure of safety-related microprocessors does not cause a HAZARD		N/A
	Loss of processor memory battery power does not lead to a HAZARD	(see Form B.1)	N/A
14.105	Asbestos		P
	No parts of asbestos used		P

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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
Model SA-252F					
4.4.2.102	6	The equipment operates at 90% and 110% of the rated voltage (198Vac and 264Vac) for one cycle. The voltage then set to 90% of the rated voltage for 5 min. The voltage is reduced gradually at a rate of approximately 10V per min until the equipment fails to operate normally. The voltage then reset to the rated voltage with the equipment still switched on	1 hr 29 min	Pressure valve works at 2.5 bar. The unit shut down after 50 minutes and the alarm works.	P
4.4.2.103	7	Failure of other supply (Heating without water)	15 min	The equipment shut down at 109V. It works normally after reset to rated voltage.	P
Model SA-300VLA					
4.4.2.102	14	The equipment operates at 90% and 110% of the rated voltage (198Vac and 264Vac) for one cycle. The voltage then set to 90% of the rated voltage for 5 min. The voltage is reduced gradually at a rate of approximately 10V per min until the equipment fails to operate normally. The voltage then reset to the rated voltage with the equipment still switched on	15 min	The equipment shut down at 118V. It works normally after reset to rated voltage.	P
4.4.2.103	15	Failure of other supply (Heating without water)	1 hr	Unit stops heating and stays at “ add water” function	P
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:					

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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:

Handle with light load only. Force to put the load into the chamber or remove it from the chamber is far less than 250N.

IEC / EN 61010-2-040			
Clause	Requirement - Test	Result - Remark	Verdict

7.101	**TABLE: Doors, conveyors etc.**		**Form B.3**	P
Description where test applied	Force (N)	Interlocked Yes / No	Remark	Verdict
Pull the door during normal operation	1000 N	Yes	Not possible to open	P

Supplementary information:

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

Supplementary information:

IEC / EN 61010-2-040			
Clause	Requirement - Test	Result - Remark	Verdict

11.7.4	**TABLE: Overpressure safety device**			**Form B.4**	P
Part	Maximum permissible working pressure MPa	Pressure inside PRESSURE VESSEL MPa	Safety device operating YES / NO	Remark	
Overpressure safety device	0.22 MPa (2.2 bar)	0.2 MPa	No	passed	

Supplementary information:

IEC / EN 61010-2-040			
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:
No obvious sound level during the operation

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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:

	TABLE 1: - List of components and circuits relied on for safety					N/A
Object / Part No.	Application/function	Manufacturer / trademark (NOTE 1)	Type / model	Technical data (NOTE 2)	Standard (Edition / Year)	Mark(s) of conformity evidence of acceptance (NOTE 3 and 4)
See the critical components list in the report for the general standard						

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