

TEST REPORT

Product name:	Steam Sterilizer
Model:	STE-45-T
Sample Number:	2017040502
Sampling Method:	Engineering Sample
Standard :	EN 13060:2014
Test Duration:	2017-04-05~2017-04-07
Test Report No.:	2017-TR011

Ningbo ican machines Co., Ltd.

Report No.: 2017-TR011

Product Name	Steam Sterilizer		
Type / model	STE-45-T	Test procedure	Design verification
Applicant	Production and Technique Department		
Manufacturer	Ningbo ican machines Co., Ltd.		
Sampling Method	Engineering Sample	Sampling Place	Final Store Products
Sampling Date	2017-04-05	Sample Quantity	1 pc
Sample Lot /Serial Number	2017040502		
Test Standard	EN 13060:2014		
Test Item	All Items		
Test Place	Test Lab of Production and technique department		
Test Duration	2017-04-05~2017-04-07		
Test Results	The equipment under test is in complies with the requirements of standard EN 13060:2014 "Small steam sterilizers".		

Tester: Ge Huankong

Date: 2017.04.07

Reviewer: Lin Hui

Date: 2017.04.07

Test item particulars.....:

Type of item tested.....: Laboratory Equipment
 Description of equipment function.....: Sterilization
 Intended use.....: Sterilization
 Installation/overvoltage category.....: In doors / category II
 Pollution degree.....: Degree 2
 Environmental rating.....: Standard
 Equipment mobility.....: Stationary
 Connection to mains supply.....: Detachable cord set
 Operating conditions.....: Continuous
 Overall size of the equipment (L × W × H).....: 640 mmX 560mmX 840mm
 Mass of the equipment (kg).....: 120 kg
 Marked degree of protection to IEC 60529.....: No marking.

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)

General remarks:

The test results presented in this report relate only to the item(s) tested.

“(see remark #)” refers to a remark appended to the report.

“(see Annex #)” refers to an annex appended to the report.

“(see Form A.#)” refers to a table appended to the report.

Throughout this report a point is used as the decimal separator.

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict

4	General technical requirements		
4.1	Dimensions The useable space shall be insufficient in size to accommodate a sterilization module.	$\Phi 319 \times 617$	P
4.2	Materials The materials used for components in contact with steam, including instrumentation, shall: ---Resist the attack of steam and condensate; ---Not lead to deterioration of the quality of the steam; Any material used shall not release any substance in such quantities that it could constitute an environmental or health risk.	Canister: stainless steel 304; Joint tube; clinical silica gel; Material of heat preservation: alumina silicate	P
4.3	Design and construction		
4.3.1	General		
4.3.1.1	Transport, storage and packaging conditions for which the device is designed and manufactured shall be specified to ensure its characteristics and performance for intended use are not adversely affected.	Accord with it	P
4.3.1.2	The sterilizer package should be designed to protect the sterilizer and preserve its characteristics during intended transport and storage.	Accord with it	P
4.3.1.3	The sterilizer and its components (if applicable) shall be packed for transportation and storage in a way that, when handled or transported, all parts of the sterilizer shall remain in their position and orientation so that the sterilizer remains stable and no moving part can cause a hazard.	Accord with it	P
4.3.1.4	Where the weight, size or shape of the sterilizer or its various components prevents them from being moved by hand, the sterilizer, or each component shall either be fitted with attachments for	Accord with it	P

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	lifting gear, or be designed so that it can be fitted with such attachments, or be shaped in such a way that standard lifting gear can easily be attached for safe handling.		
4.3.1.5	The design and construction of the device shall be such as to avoid errors in connection, fitting, refitting or direction of movement of internal and external parts or devices, which could be a source of risk. Should this not be possible, information on connection, fitting, refitting and direction of movement shall be given on/by the parts.	Accord with it	P
4.3.2	Doors and locking devices		
4.3.2.1	Doors and locking devices shall be designed according to EN 61010-2-040:2005, 7.101.	Accord with it	P
4.3.2.2	The door shall be capable of being closed without being locked, so that it can be re-opened and closed before a sterilization cycle is initiated. When the door is fully closed, it shall be in the position required for it to be locked. When the door is locked, separate actions shall be required to unlock and to open the door.	Accord with it	P
4.3.2.3	When fitted, the door seal shall permit ease of cleaning of the contact surfaces and seal replacement.	Accord with it	P
4.3.2.4	After cycle start it shall not be possible to open a sterilizer door before "cycle complete" is indicated, except through special intervention that will lead to a "sterilization process fault" indication.	Accord with it	P
4.3.2.5	For double ended sterilizers it shall not be possible for more than one door to be open at a time, except for maintenance purposes.	single ended sterilizers	N/A
4.3.2.6	For double ended sterilizers it shall not	single ended sterilizers	N/A

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	be possible to open the unloading door before "cycle complete" is indicated.		
4.3.3	Test connection(s)		
4.3.3.1	The sterilizer shall be equipped with at least one standard test connection.	Set up test connections	P
4.3.3.2	The test connection(s) shall have a female pipe thread conforming to G1/4 according to EN ISO 228-1.	G1/4 test connections	P
4.3.3.3	The test connection(s) shall be at a point of easy access to the chamber. The test connection(s) shall be clearly marked.	The sign is clearly	P
4.3.3.4	The steam inlet or vacuum ports and pipelines shall not be used for test connections.	Accord with it	P
4.3.4	Air filter		
4.3.4.1	The air admitted to return the sterilizer chamber to atmospheric pressure after a vacuum drying stage shall be admitted through a filter.	Accord with it	P
4.3.4.2	Air filters shall be constructed from materials compatible with steam sterilization.	Accord with it	
4.3.4.3	The filter unit shall be readily accessible.	Be readily accessible.	P
4.3.4.4	The filter shall be protected from any influence that can impair its proper function.	Accord with it	P
4.3.4.5	The filter shall retain not less than 99,5 % of particles greater than 0,30 µm.	Accord with it	P
4.3.5	Vibrations		
4.3.5.1	The design of the sterilizer shall limit vibrations to a level that does not impair the performance of the device nor cause an unacceptable health risk for any person.	Accord with it	P
4.3.5.2	Means shall be to reduce vibrations generated by components of the sterilizer, taking account of available solutions for reducing vibrations at source.	Accord with it	P
4.3.5.3	If vibrations can cause a loss of stability	Accord with it	P

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	of the sterilizer, means shall be provided for suitable fixation.		
4.3.6	Noise		
4.3.6.1	Means shall be incorporated to reduce noise generated by components of the sterilizer, taking account of available solutions for reducing noise at source.	Accord with it	P
4.3.6.2	The sound power levels as required by 7.2.6 shall be stated in the documentation (see Table 4, item nr. 22).	Accord with it	P
4.4	Instrumentation, indication and registration devices		
4.4.1	General All instruments and indicating devices specified in 4.4 shall be located where they can be viewed readily by the operator under normal operation of the sterilizer and their function shall be identified. Unless otherwise specified in this standard, the required instruments and gauges shall be readable by normal or corrected vision from a distance of 1 m and with a minimum illumination of (215 \pm 15) lx.	Accord with it	P
4.4.2	Instruments and indicators		
4.4.2.1	General Sterilizers shall be provided with the following instruments: a) sterilizer chamber temperature indicating instrument; b) sterilizer chamber pressure indicating instrument; c) jacket pressure indicating instrument (if the sterilizer is fitted with a pressurized jacket).	a) can display digital; b) can display digital; c) N/A	P
4.4.2.2	Sterilizer chamber temperature indicating instrument The chamber temperature indicating instrument shall: a) be either digital or analogue;	digital; degrees Celsius; room temperature:40°C~150°C d) $\pm 1^{\circ}\text{C}$; e) N/A	P

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	b) be graduated in degrees Celsius; c) have a scale which includes 75 ° C to 150 ° C; d) have an accuracy of better than ± 2 ° C over the scale range 75 ° C to 150 ° C; e) for analogue instruments, be graduated in divisions not greater than 2 ° C; f) for digital instruments, have a resolution better than 1 ° C; g) be adjusted to an accuracy of +0 ° C/ - 1,5 ° C at the sterilization temperature; h) when used for a control function, have a broken sensor protection that fails to safety; i) have an ambient temperature error compensation not exceeding 0,04 K/K over the scale range; j) have means of adjustment in situ by the use of a special tool, key or code without dismantling the instrument; k) have a response time $90 \tau \leq 5$ s when tested according to EN 60751:2008, 6.5.2.	f) $\leq 1^{\circ}\text{C}$; g) 0 ° C/-1.5 ° C; h) Have 2 sensors protection i) <0.04 K/K; j) Adjust temperature of by code or key k) 4S	
4.4.2.3	Sterilizer chamber pressure instrument The sterilizer chamber pressure instrument shall: a) be either digital or analogue; b) be graduated in kilopascals or bars; c) when the sterilization cycle includes a vacuum phase, have a scale which includes the range 0 kPa and 1,3 times the maximum allowable pressure or - 1 bar and 1,3 times the maximum allowable pressure, given as absolute pressure value with a zero reading at absolute vacuum or ambient pressure respectively; d) when the sterilization cycle does not	digital; in bar; figure displays pressure -1 ~ 3.00bar; N/A 0.02bar; N/A Precision of displayed figure: 0.02bar; Have 2 sensors protection <0.04K/K Adjust pressure of by code or key	P

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	<p>include a vacuum phase, have a scale which includes the range 100 kPa and 1,3 times the maximum allowable pressure or 0 bar and 1,3 times the maximum allowable pressure, given as absolute pressure value;</p> <p>e) have an accuracy of better than or equal to ± 5 kPa (0,05 bar) over the scale range;</p> <p>f) for analogue instruments, be graduated in divisions not greater than 20 kPa (0,2 bar);</p> <p>g) for digital instruments, have a resolution of better than or equal to 2 kPa (0,02 bar);</p> <p>h) when used for a control function, have a broken sensor protection that fails to safety;</p> <p>i) have an ambient temperature error compensation not exceeding 0,04 %/K over the scale range;</p> <p>j) when the sterilizer chamber pressure instrument is adjustable it shall require the use of a special tool, key or code.</p>		
4.4.2.4	<p>Jacket pressure indicating instrument</p> <p>If the sterilizer is fitted with a pressurized jacket, the jacket pressure indicating instrument shall:</p> <p>a) be either digital or analogue;</p> <p>b) be graduated in kilopascals or bars;</p> <p>c) have a scale which includes the range 100 kPa and 1,3 times the maximum allowable pressure, or 0 bar and 1,3 times the maximum allowable pressure, given as absolute pressure value;</p> <p>d) have an accuracy of better than or equal to ± 10 kPa (0,10 bar) over the scale range;</p> <p>e) for analogue instruments, be graduated in divisions not greater than 20 kPa (0,2 bar);</p>	the sterilizer isn't fitted with a pressurized jacket;	N/A

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	f) for digital instruments, have a resolution of better than or equal to 10 kPa (0,1 bar); g) when used for a control function, have a broken sensor protection that fails to safety; h) have an ambient temperature error compensation not exceeding 0,04 %/K over the scale range; i) when the jacket pressure indicating instrument is adjustable it shall require the use of a special tool, key or code.		
4.4.3	Indicating devices		
4.4.3.1	Loading side of the sterilizer In addition to the instruments identified in 4.4.2.1, the loading side of the sterilizer shall be provided with indicating devices visible from the operating position providing at least the following information: a) “door(s) locked” ; b) “in progress” ; c) “cycle complete” ; d) “sterilization process fault” ; e) sterilization cycle selected and the type of cycle according to this standard; f) sterilization cycle counter (see 4.4.3.4). The "cycle complete" indication shall be cancelled when the door-opening process has been initiated.	The Indicating devices of the sterilizer included these information.	P
4.4.3.2	Double ended sterilizer In addition to 4.4.3.1 the unloading side of a double ended sterilizer shall be provided with indicating devices visible from the operating position providing the following information: a) sterilizer chamber pressure; b) “doors locked” ; c) “in progress” ; d) “cycle complete” ; e) “sterilization process fault” .		N/A

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	The "cycle complete" indication shall be cancelled when the opening of the door has been initiated.		
4.4.3.3	Acoustic signals When fitted, the acoustic signal shall be time limited to a maximum of 30 s and/or it shall be possible to interrupt it.	25s	P
4.4.3.4	Cycle counter The cycle counter shall: <ul style="list-style-type: none"> — indicate the total number of all cycles started; — be capable of displaying a minimum of five digits with each digit making a full count of 0 to 9. The cycle counter shall not be capable of being reset or altered by the user or operator.	Accord with it	P
4.4.3.5	Air leak indication If the sterilizer utilizes a vacuum stage for air removal, it shall be equipped with an automated air leakage rate test cycle. This test cycle will operate between two pressures, one of which shall be equal to or lower than the lowest pressure during air removal and steam penetration considering all available sterilization cycles. An air leakage rate signified by a pressure change greater than 0,13 kPa/min (1,3 mbar/min) shall result in a "sterilization process fault" indication.	Accord with it	P
4.4.4	Recorders and recordings		
4.4.4.1	General		
4.4.4.1.1	Sterilizers shall be provided with a recorder independent from the control system. Alternatively a process evaluation system according to 4.4.5 shall be installed. If the sterilizer is fitted with a process evaluation system, a registration unit for documentation of its results should also be fitted.	Accord with it	P

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	Recorders can be either analogue or digital, in-built or external or networked.		
4.4.4.1.2	All data sampled during the sterilization cycle shall be represented in the record. Records shall be readable by normal or corrected vision from a distance of 250 mm and with a minimum illumination of (215 ± 15) lx.	Accord with it	P
4.4.4.1.3	The following parameters shall be recorded or, alternatively, evaluated by a process evaluation system according to 4.4.5: — pressure, independent from the process controller, and the temperature signal taken from the process controller; or — temperature, independent from the process controller, and the pressure signal taken from the process controller; — time, independent from the process controller or automatically verified to another source. If a process evaluation system is used it shall comply with 4.4.5.	Accord with it	P
4.4.4.1.4	Analogue systems to be considered independent shall be completely separate. Digital systems to be considered independent shall have separate sensors, amplifiers and AD converters. If in addition a process evaluation system is used, independence is not required.	The analogue systems to be considered independent be completely separate.	P
4.4.4.1.5	Time records shall have a measurement error not exceeding 1 % of a defined time interval of the operating cycle. Time records should be graduated in hours, minutes and seconds as applicable.	Accord with it	P
4.4.4.2	Recorders producing analogue records		
4.4.4.2	Temperature and pressure shall be	Recorders producing digital records	N/A

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
.1	recorded on the same chart with the same time scale		
4.4.4.2 .2	For recorders producing analogue records a time scale of not less than 4 mm/min shall be used. If times are marked, units shall be either in seconds or minutes or multiples thereof.	Recorders producing digital records	N/A
4.4.4.4 2.3	Temperature recorders producing analogue records shall: a) have a chart graduated in degrees Celsius; b) have a chart graduated in divisions not greater than 2 K; c) have a scale which includes the range 50 ° C to 150 ° C; d) have an accuracy of $\pm 1\%$ or better over the scale range 50 ° C to 150 ° C; e) have a resolution of 1 K or better; f) have the means to be adjusted within ± 1 K at the sterilization temperature; g) sample each channel at least once every 2,5 s; h) print data from each channel at least once 2,5 s.	Recorders producing digital records	N/A
4.4.4.2 .4	Pressure recorders producing analogue records shall: a) have a chart graduated in kilopascals or bars; b) have a scale which includes 0 kPa to 400 kPa (- 1 bar to 3 bar); c) indicate zero either at absolute vacuum or at ambient pressure respectively; d) have an accuracy of $\pm 1,6\%$ or better over the scale range 0 kPa to 400 kPa (- 1 bar to 3 bar); e) when the sterilization cycle does not include a vacuum phase, have a scale which includes 100 kPa to 400 kPa (0 bar to 3 bar);	Recorders producing digital records	N/A

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	<p>f) when the sterilization cycle does not include a vacuum phase, have an accuracy of $\pm 1,6$ % or better over the scale range 100 kPa to 400 kPa (0 bar to 3 bar);</p> <p>g) sample each channel at least once every 2,5 s;</p> <p>h) print data from each channel at least once every 2,5 s;</p> <p>i) have a chart with graduated divisions not greater than 20 kPa (0,2 bar);</p> <p>j) have a resolution of 5 kPa (0,05 bar) or better;</p> <p>k) be adjusted to an accuracy of ± 5 kPa ($\pm 0,05$ bar) or better at the operating pressure.</p> <p>In case the sterilization temperature is higher than 134 ° C the scale for pressure recording systems shall be extended accordingly.</p>		
4.4.4.3	Recorders producing digital records		
4.4.4.3.1	Not all data sampled to produce a digital record needs to be printed but, the minimum recording shall include at least the information according to Table 2 for the specimen sterilization cycle in Figure 1.	Accord with it	P
4.4.4.3.2	<p>Temperature recorders producing digital records shall:</p> <p>a) have alpha numeric characters;</p> <p>b) have data identified by text or symbols or both;</p> <p>c) have the data presented as text or figures or both;</p> <p>d) have a paper width which has a space for a minimum of 15 characters per line;</p> <p>e) have a range which includes 50 ° C to 150 ° C;</p> <p>f) have an accuracy of ± 1 % or better over the range 50 ° C to 150 ° C;</p> <p>g) have the means to be adjusted within</p>	<p>alpha numeric characters;</p> <p>text;</p> <p>text;</p> <p>24 characters per line;</p> <p>40 ° C to 150 ° C;</p> <p>$< \pm 1\%$;</p> <p>$\pm 1k$;</p> <p>0.1k;</p> <p>1s.</p>	P

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	<p>± 1 K at the sterilization temperature;</p> <p>h) have a resolution of 0,1 K or better;</p> <p>i) sample each channel at least once every 2,5 s.</p>		
4.4.4.3.3	<p>Pressure recorders producing digital records shall:</p> <p>a) have alpha numeric characters;</p> <p>b) have data identified by text or symbols or both;</p> <p>c) have the data presented as text or figures or both;</p> <p>d) have a paper width which has a space for a minimum of 15 characters per line;</p> <p>e) have a range which includes 0 kPa to 400 kPa (- 1 bar to 3 bar);</p> <p>BS EN 13060:2014 EN 13060:2014 (E) 23</p> <p>f) when the sterilization cycle does not include a vacuum phase, have a scale which includes 100 kPa to 400 kPa (0 bar to 3 bar);</p> <p>g) have an accuracy of $\pm 1,6$ % or better over the range 0 kPa to 400 kPa (- 1 bar to 3 bar);</p> <p>h) when the sterilization cycle does not include a vacuum phase, have an accuracy of $\pm 1,6$ % or better over the scale range 100 kPa to 400 kPa (0 bar to 3 bar);</p> <p>i) be adjusted to an accuracy of better than or equal to ± 5 kPa ($\pm 0,05$ bar) at the operating pressure;</p> <p>j) sample each channel at least once every 2,5 s;</p> <p>k) have a resolution of 1 kPa (10 mbar) or better.</p> <p>In case the sterilization temperature is higher than 134 ° C the scale for pressure recording systems shall be extended accordingly.</p>	<p>alpha numeric characters;</p> <p>text;</p> <p>text;</p> <p>24 characters per line;</p> <p>-1bar~3.00bar;</p> <p>N/A;</p> <p>$< \pm 1.6\%$;</p> <p>N/A;</p> <p>0.02bar;</p> <p>1s;</p> <p>0.01bar.</p>	P
4.4.5	Process evaluation system		

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
4.4.5.1	<p>If fitted the process evaluation system shall:</p> <p>a) compare with a validated cycle any change in pressure and temperature and the period of the cycle during which the change occurs; any change beyond programmed limits shall cause a "sterilization process fault" to be indicated;</p> <p>b) compare two independent temperature sensors, which may be those associated with the sterilizer chamber temperature indicating instrument and the temperature recorder; or</p> <p>c) be capable of comparing the theoretical steam temperature with the chamber temperature during the holding time;</p> <p>d) have a temperature measuring system accuracy better than or equal to that specified for the chamber temperature indicating instrument;</p> <p>e) have a pressure measuring system accuracy better than or equal to that specified for the chamber pressure indicating instrument;</p> <p>f) have a time measuring system with an accuracy of $\pm 1\%$ or better;</p> <p>g) operate to the specified limits taking into account the process evaluation system accuracy;</p> <p>h) have been verified for its intended reaction upon specified process failures.</p>	No fitted the process evaluation system	N/A
4.4.5.2	<p>If a recorder is fitted to the process evaluation system, the following data shall be recorded:</p> <ul style="list-style-type: none"> — sterilizer identification; — date; — program; — cycle number; — process satisfactory, or not 	No fitted the process evaluation system	N/A

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	satisfactory. NOTE See Annex B for additional information on process evaluation systems.		
4.5	Control systems		
4.5.1	Process control		
4.5.1.1	The sterilization process can be either temperature or pressure controlled. In both cases the process control system shall ensure the presence of saturated steam.	Accord with it	P
4.5.1.2	The sterilizer shall be provided with an automatic controller. The automatic controller shall be programmed with the pre-set cycle parameters for each stage of the sterilization cycle. It shall not be possible to change cycle parameters during a cycle. The pre-set cycle parameters shall only be adjustable by use of a special key, tool or code. The automatic controller shall be capable of monitoring the specified pre-set cycle parameters.	Accord with it	P
4.5.1.3	For a double ended sterilizer the controls used to start the sterilization cycle shall be located on the loading side of the sterilizer.	single ended sterilizer	N/A
4.5.1.4	If the sterilizer is designed to retain water in the chamber after completion of the cycle, the visual indication “ cycle complete” shall be activated only if the water will not boil at the moment of unsealing the door (see 4.4.3) and there is no retained pressure in the chamber’ .	No retain water	N/A
4.5.1.5	Means shall be provided for the operator to terminate the sterilization cycle without causing a hazardous situation. When the sterilization cycle is terminated by the operator, a "sterilization process fault" shall be indicated.	Accord with it	P
4.5.1.6	A separate test cycle shall be provided if	No difference between the exposure	N/A

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	the exposure time specified for the indicator used to determine the efficacy of steam penetration is different than the plateau period used for the sterilization cycle used for production. This cycle shall have the same air removal stage as the one used for the sterilization cycle used for production.	time specified for the indicator and plateau period used for production	
4.5.2	Performance verification It shall be possible to assess the performance of an operating cycle: <ul style="list-style-type: none"> — from readings noted from the sterilizer indicators and; BS EN 13060:2014 EN 13060:2014 (E) 26 — from readings obtained from a recorder; or — automatically by a process evaluation system. 	Accord with it	P
4.5.3	Sterilization process fault indication systems		
4.5.3.1	The values for all cycle variables shall be specified. These shall include, but are not limited to: <ul style="list-style-type: none"> — the switch points of all vacuum and steam pressure pulses, — the sterilization pressure and temperature, and — the holding times related to the available sterilization cycles (see 4.8.2). 	Evaluation of the cycle performance	P
4.5.3.2	The automatic controller shall cause a visual indication that a "sterilization process fault" has occurred and not cause a hazardous situation, if: <ul style="list-style-type: none"> — the values of cycle variables are outside the specified limits; — a power failure occurs; — a failure of a service occurs. 	Accord with it	P
4.5.3.3	If the sterilizer is fitted with a printer for recording cycle parameters, the indication of a "sterilization process fault" shall also be printed.	Failure display can be printed	P

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
4.5.3.4	After a "sterilization process fault" has been indicated, the automatic controller shall allow the sterilization cycle to be terminated without causing a hazardous situation. To make the sterilizer ready for use again the use of a special tool, key or code shall be required.	Accord with it	P
4.5.3.5	A visual display of a "sterilization process fault" shall continue at least until an action different from the normal operation of the sterilizer is carried out to reset the system.	Accord with it	P
4.5.3.6	For double ended sterilizers, a "sterilization process fault" shall be indicated at both ends and it shall not be possible to open the unloading door if a "sterilization process fault" is indicated (see also 4.4.3.2).	single ended sterilizers	N/A
4.5.4	Software		
4.5.4.1	Software for automatic controllers shall be demonstrated to function as intended.	Accord with it	P
4.5.4.2	Classification of software with respect to safety shall be established through risk assessment.	Accord with it	P
4.5.4.3	Software parts related to safety of patients, users or any other persons shall be verified and validated using methods according to the state of art. The methods used in the validation and verification process shall be justified and documented.	Accord with it	P
4.6	Process		
4.6.1	General For moist heat sterilization using steam as the sterilant it is essential that all surfaces to be sterilized are subjected to saturated steam at a predetermined temperature for a predetermined period of time. Proper steam penetration into the load and — if applicable into the individual items —	Accord with it	P

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	therefore is essential. Steam penetration requires adequate air removal. The requirements listed below and the associated test methods address factors and parameters that may promote or inhibit steam penetration and therefore the efficacy of the sterilization process.		
4.6.2	Sterilization temperature, sterilization temperature band, holding time The sterilization temperature, the sterilization temperature band and the holding time shall be pre-set, specified and stated in the user instructions (see 4.8.3) for each available sterilization cycle.	Under cover to user instructions	P
4.6.3	Time-temperature relationships The sterilizer shall provide sterilization conditions according to, or alternatives which can be proven to be equivalent to, the time temperature relationships given in Table 3. In case the sterilization temperature is higher than 134 ° C the scale for pressure recording systems shall be extended accordingly.	121°C--30min; 134°C--8min	P
4.6.4	Equilibration time The equilibration time shall not exceed 15 s. An equilibration time not exceeding 30 s is acceptable if: <ul style="list-style-type: none"> — the rise of the theoretical steam temperature during the last 10 K of the heating stage is less than 8 K/min but greater than 1 K/min; — during the last 10 K of the heating stage all temperatures measured in the chamber and the load as well as the theoretical steam temperature do not differ from one another by more than 2 K. 	Equilibration time<30s	P
4.7	Services and local environment		

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
4.7.1	General Sterilizers shall be designed to comply with the requirements of this standard when operated under the environmental conditions for the equipment.	Accord with it	P
4.7.2	Electrical supply The sterilizer shall be designed to operate when the mains supply voltage is maintained within $\pm 10\%$ of the nominal supply voltage.	Electrical supply within 10%	P
4.7.3	Water supply for steam generation in the sterilizer		
4.7.3.1	The sterilizer shall be designed to function with water free from contaminants in a concentration that could impair the sterilization process or harm the sterilizer or the sterilization load.	distilled water	P
4.7.3.2	If a water reservoir is fitted: a) the reservoir and associated pipe work shall be fitted with a valve or other device to allow draining by the operator or the automatic control system; b) the reservoir shall be large enough to contain sufficient water for the running of a complete sterilization cycle or the number of consecutive operating cycles specified to be performed with the test load having the maximum steam consumption; c) the reservoir shall be vented and its design shall facilitate cleaning, inspection and filling; d) means shall be provided to indicate whether the water in the reservoir is sufficient for an operating cycle; e) the sterilizer shall not be capable of starting a cycle if there is insufficient water in the reservoir; f) the water reservoirs shall be designed to prevent back siphoning.	Manual valve; Accord with it; Accord with it; There will be alarm and display if there is insufficient water in the reservoir; Accord with it; collocate uni-directional valve of preventing against reverse inbreathing	P
4.7.4	Drains	<60 °C	P

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	The sterilizer shall be designed so that the temperature of water or vapour drained to an external drainage system does not exceed 100 ° C.		
4.7.5	Compressed air for control systems When applicable the sterilizer shall be designed to operate with a compressed air supply, free of liquid water, filtered to 25 µm and free of oil droplets greater than 2 µm. The permissible air pressure range shall be stated.	No permissible air	N/A
4.7.6	Water used other than for steam generation When water is used for cooling purposes and/or in a vacuum system the sterilizer shall be designed to be capable of operating with water which is of potable quality and supplied at a temperature in the range as specified, including 15 ° C.	No such water	N/A
4.7.7	External steam supply to the sterilizer If used, the external steam supply to the sterilizers shall be in accordance with EN 285:2006+A2:2009, 13.3.	No external steam	N/A
4.8	Information to be provided		
4.8.1	General The information given in the manuals shall be according to EN 1041. Where necessary, further instructions shall be given on the potential risks related to incorrect connection, fitting, refitting parts or direction of movement. The information shall be given in the language as required by applicable regulations at the installation site. The information provided shall address the needs of users with different technical knowledge, education and training. The information provided in Table 4 shall be provided as individual manuals or	according to EN 1041	P

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	alternatively be combined, as deemed appropriate for delivery (see 4.8.2, 4.8.3, and 4.8.4).		
4.8.2	Pre-purchase information The information provided in the pre-purchase information column of Table 4 shall be provided upon demand.	Accord with it	P
4.8.3	Instructions for Use When the sterilizer is delivered, at least the information specified in the instruction manual column of Table 4 shall be provided and shall include the date of issue or the latest revision of the respective documents.	Accord with it	P
4.8.4	Technical Information When the sterilizer is delivered, at least the information specified in the technical information column of Table 4 shall be provided and shall include the date of issue or the latest revision of the respective documents.	Accord with it	P
4.9	Marking		
4.9.1	Marking of the pressure vessel The pressure vessel shall be marked according to EN 61010-1:2010, Clause 5, as modified by EN 61010-2-040:2005, Clause 5.	Note according to the requirements of EN61010-2-040	P
4.9.2	Marking of the sterilizer and the packaging		
4.9.2.1	Instructions for handling, unpacking, transport and storage shall be clearly indicated on the outside of the package.	Accord with it	P
4.9.2.2	The sterilizer shall provide the following information, clearly visible from the operating position and using where appropriate, suitable standardised symbols (see e.g. ISO 15223-1 and EN 61010-1:2010, Clause 5): a) identification of the function of the instruments and controls; b) the residual risks warnings; c) if appropriate indication of the water	Accord with it	P

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	quality to be used.		
4.9.2.3	<p>An identification plate that is clearly visible shall be affixed to the sterilizer frame or body and shall bear the following information:</p> <p>a) name and address of manufacturer and (if applicable) the legal entity responsible for introducing the product in the EU market;</p> <p>b) name and address of the authorized representative in the Community in cases where the manufacturer does not have a registered place of business in the Community;</p> <p>c) model/type identification;</p> <p>d) serial number;</p> <p>e) year of manufacture;</p> <p>f) rated voltage;</p> <p>g) current type;</p> <p>h) rated frequency;</p> <p>i) maximum current or power;</p> <p>j) CE-mark, accompanied by the European registration number(s) of the notified body or bodies engaged for medical device and pressure equipment as applicable;</p> <p>k) warning symbols.</p>	Accord with it	P
4.10	<p>Accessories</p> <p>The sterilizer shall be equipped with chamber furniture equivalent to the type used in the type test and suitable means to remove the load from the chamber.</p>	Accord with it	P
5	Performance requirements		
5.1	<p>General</p> <p>An explanation and rationale for the performance requirements and the respective tests are given in Annex F.</p>		
5.2	<p>Air leakage rate</p> <p>If the sterilizer utilizes a vacuum stage for air removal in any sterilization cycle, the rate of air leakage into the sterilizer chamber during periods of vacuum shall</p>	0.11kPa/min	P

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	not cause the rate of pressure rise to exceed 0,13 kPa/min (1,3 mbar/min) when tested in accordance with 10.2.		
5.3	Attainment of the sterilization conditions		
5.3.1	<p>The presence of saturated steam in the usable chamber space and the load is deemed to have been achieved when, throughout the holding time, all temperatures measured in the usable chamber space and the load:</p> <ul style="list-style-type: none"> — are not lower than the sterilization temperature; — are not more than 3 K above the sterilization temperature. <p>For products designed and placed on the market prior to publication of this edition of EN 13060 the 4K band as specified by EN 13060:2004+A2:2010, 5.3.1 may apply.</p> <ul style="list-style-type: none"> — Do not differ from each other by more than 2 K. <p>The theoretical steam temperature which is calculated from the measured pressure shall also be considered as a measured temperature.</p>	<p>Accord with it</p> <p>It is 2.7K above the sterilization temperature.</p> <p>The same time the maximum temperature difference between each point is 1.7K</p>	P
5.3.2	For narrow lumen and simple hollow items, the presence of saturated steam is deemed to be adequately demonstrated by satisfactory colour change in the chemical indicator system used, as specified for the indicator system (see 10.6.2, 10.7.2).	Color change of the indicative adhesive tape achieve the requirements(3M)	P
5.3.3	To justify the minimum performance requirements for sterilizers and sterilization of narrow lumen or simple hollow items according to this standard, PCDs as specified in 8.10 or 8.11, respectively, shall be used.	Accord with it	P
5.3.4	For porous load tests only, during the plateau period the temperature, if measured within 50 mm above the test	Accord with it	P

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	load, shall not exceed the temperature measured at the reference measurement point of the sterilizer chamber by more than 5 ° C for the first 60 s and 2 ° C for the remaining period.		
5.4	Product compatibility		
5.4.1	Dynamic sterilizer chamber pressure test The rate of pressure change during any part of the sterilization cycle shall not exceed 10 bar/min for any 2 s interval when tested in accordance with 10.3.	Accord with it	P
5.4.2	Maximum allowable temperature The temperature in the usable chamber space of the empty chamber shall not exceed the highest value of the temperature band when tested in accordance with 10.4.	Accord with it	P
5.5	Drying		
5.5.1	For wrapped loads, any remaining moisture shall not lead to wet packages and shall not result in detrimental effects on the sterilization load. Any remaining water droplets on the inner side of the film of laminate pouch shall evaporate within 5 min of end of cycle.	Not more than 5min	P
5.5.2	The change in moisture content of the load shall comply with 5.5.3 and 5.5.4 respectively when “cycle complete” is indicated.	No more than 0.2%	P
5.5.3	For a solid load the moisture content shall not exceed 0,2 % when tested in accordance with 10.11.	No more than 0.2%	P
5.5.4	For a porous load the moisture content shall not exceed 1,0 % when tested in accordance with 10.12.	No more than 1.0%	P
5.6	Microbicidal efficacy Microbiological tests are optional. If performed, as specified in 10.15, 10.16, 10.17, 10.18, 10.19 or 10.20, the sterilized biological indicator or the	Test according to 10.15	P

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	sterilized inoculated carrier shall not show growth. The biological indicator positive controls shall show growth.		
5.7	Non-condensable gases When a non-condensable gas test is performed, as described in 10.14, the percentage ratio of the volume of non-condensable gases to the volume of condensate collected shall be not greater than 3,5 %.	No more than 3.5%	P
6	Safety, risk control and usability		
6.1	General requirements If applicable for the purpose of this standard: a) For marking and documentation sterilizers shall comply with EN 61010-1:2010, Clause 5, as modified by EN 61010-2-040:2005, Clause 5. b) For the protection against electric shock sterilizers shall comply with EN 61010-1:2010, Clause 4 and Clause 6, Annex A, Annex B, Annex C, Annex D, Annex F, Annex H, Annex K, as modified by EN 61010-2-040:2005, Clause 6. c) For the protection against mechanical hazards and hazards related to mechanical functions sterilizers shall comply with EN 61010-1:2010, Clause 4 and Clause 7, as modified by EN 61010-2-040:2005, Clause 4 and Clause 7. d) For the protection against hazards due to mechanical resistance to shock and impact sterilizers shall comply with EN 61010-1:2010, Clause 4 (except 4.4) and Clause 8. e) For the protection against the spread of fire sterilizers shall comply with EN 61010-1:2010, Clause 4 and Clause 9 (except 9.5), as modified by EN 61010-2-040:2005, Clause 4 and Clause 9.	Accord with it	P

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	<p>f) For the protection against hazards in relation to equipment temperature limits and resistance to heat sterilizers shall comply with EN 61010-1:2010, Clause 4 and Clause 10, as modified by EN 61010-2-040:2005, Clause 4 and Clause 10.</p> <p>g) For the protection against hazards from fluids sterilizers shall comply with EN 61010-1:2010, Clause 4 and Clause 11, as modified by EN 61010-2-040:2005, Clause 4 and Clause 11.</p> <p>BS EN 13060:2014 EN 13060:2014 (E) 36</p> <p>h) For the protection against radiation, including laser sources, sterilizers shall comply with EN 61010-1:2010, Clause 4, 12.1, 12.3 and 12.6.</p> <p>i) For the protection against liberated gases, substances, explosion and implosion sterilizers shall comply with EN 61010-1:2010, Clause 4 and 13.2.2, as modified by EN 61010-2-040:2005, Clause 4, 13.1.102 and 13.101.6.</p> <p>j) For the protection against hazards related to components sterilizers shall comply with EN 61010-1:2010, Clause 4 and Clause 14, as modified by EN 61010-2-040:2005, Clause 4 and Clause 14.</p> <p>k) For the protection by interlocks sterilizers shall comply with EN 61010-1:2010, Clause 4 and Clause 15.</p> <p>l) For the protection against hazards resulting from application sterilizers shall comply with EN 61010-1:2010, Clause 16.</p> <p>m) For the protection against hazards in relation to safety for unfired pressure equipment and assemblies sterilizers shall comply with all parts of EN 13445</p>		

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	series and EN 764-7 that are appropriate.		
6.2	Requirements for EMC Sterilizers shall comply with EN 61326-1:2013 regarding electromagnetic compatibility (EMC).	Accord with it	P
6.2.1	Sterilizers operating in areas intended for medical electrical equipment or in the vicinity of other sensitive equipment shall be regarded as class B equipment as specified by EN 61326-1:2013.	Accord with it	P
6.2.2	The immunity performance criteria selected shall ensure that sterilizer performance as specified by Clause 5 of this standard is met when exposed to disturbance phenomena of EN 61326-1:2013, Table 1.	Accord with it	P
6.3	Requirements for pressure equipment		
6.3.1	Pressure vessels shall comply with all parts of EN 13445 series that are appropriate for safety purposes for pressure equipment. Other pressure equipment standards may apply if equivalence with respect to safety is verified.	Accord with it	P
6.3.2	For sterilizers excluded from Pressure Equipment Directive 97/23/EC, the safety devices, or their relevant components shall: a) be either fail-safe, have redundancy or be self-diagnostic; b) be independent from other safety functions, unless the other safety functions are proven not to be affected by these safety devices or their relevant functions; c) have a protection level of at least IP 31 according to EN 60529; d) have safety valves complying with EN ISO 4126-1; e) have safety valves for steam and	Accord with it	P

EN 13060:2014			
Clause	Requirement-Test	Result-Remark	Verdict
	compressed air provided with means for manual testing, which shall be arranged such that the valves can be lifted off their seats when operating under pressure. When the Pressure Equipment Directive 97/23/EC is not applicable, national regulations can apply.		
6.4	Requirements for risk control		
6.4.1	Risk assessment and risk control for sterilizer design and software shall be performed following the procedures and requirements given in EN ISO 14971. Specific requirements and results shall be established and documented. For products designed and placed on the market prior to publication of this edition of EN 13060 other standards may apply instead of EN ISO 14971	Accord with it	P
6.4.2	Risk analysis shall address the specific sterilizer design and features. Measures taken for risk reduction shall consider aspects as user knowledge, experience, training, ergonomics and usability.	Accord with it	P

End of the test report