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TEST REPORT

Test Report No: RZ12030012

Test object: Syringe Pump

Manufacturer: Sino Medical-Device Technology Co., Ltd.

Applicant: Sino Medical-Device Technology Co., Ltd.

Test Type: Registration ( )

Registered Supplement ( )

Others (√) Certification Test

Guangzhou Medical Instruments Quality Surveillance and Inspection Center of State Food and Drug Administration

Digitally signed by Sula Constantin
Date: 2019.06.25 10:09:22 EEST
Reason: MoldSign Signature
Location: Moldova

Guangzhou Medical Instruments Quality Surveillance and Inspection Center of State Food and Drug Administration

Initial Page of Test Report

Name of Samples	Syringe Pump Send-off (√) Spot check ( )	Samples' Serial №	RZ12030012
Trademark	SINOMDT	Model / Type	SN-50T66R
Client	Sino Medical-Device Technology Co., Ltd.	Test Type	Certification Test
Client's Address	6th Floor, Building15, Majialong Industry Zone, Nanshan District, Shenzhen, P.R.China	Products' № / Lot №	/
Manufacturer	Sino Medical-Device Technology Co., Ltd.	Sampling Bill №	/
Corporation being inspected	Sino Medical-Device Technology Co., Ltd.	Producing date	/
Sampled by	/	Samples' Quantity	1 set
Sampled Place	/	Cardinal Number of Samples	/
Sampled Date	/	Test Place	Self-laboratory
Samples' Accepting Date	2012.04.25	Test Date	2012.04.25~2012.08.13
Test Items	The whole items		
Test According to	IEC 60601-1-8:2006		
Test Conclusion	All the test items of this product are in accordance with the requirements of IEC 60601-1-8:2006. Conclusion: Pass. (Stamps of Test Organization) Issued Date: 二〇一二 YY 监督检验中心 MM 检验专用章 DD		
Remarks	1. / means blank. 2.By information and sample inspecting, the models SN-50F66、SN-50F66R、SN-50T66、SN-50C66、SN-50C66R、SN-50C66T、SN-50C66TR and SN-50T66R are in accord in principle, structure of circuit, they differ only in appearance and some auxiliary functions. So the model SN-50T66R can cover the models SN-50F66、SN-50F66R、SN-50T66、SN-50C66、SN-50C66R、SN-50C66T、SN-50C66TR.		

Approved by: _____ **Reviewed by:** 胡昌明 **Tested by:** _____

Headship: 第2

Test Report

GENERAL INFORMATION	
Test item particulars (see also clause 5):	
Classification of installation and use ..... :	Portable
Supply connection .....:	Detachable power supply cord Internally powered
Accessories and detachables parts included in the evaluation .....:	User Manual
Options included .....:	User Manual
Possible test case verdicts:	
- test case does not apply to the test object .....:N / A	
- test object does meet the requirement.....:P	
- test object does not meet the requirement .....:F	
Abbreviations used in the report:	
- normal condition.....:N.C.	- single fault condition .....:S.F.C.
- operational insulation .....:OP	- basic insulation .....:BI
- basic insulation between parts of opposite polarity .:BOP	- supplementary insulation.....:SI
- double insulation .....:DI	- reinforced insulation.....:RI

General remarks:

"(see Attachment #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
Throughout this report a point is used as the decimal separator.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Summary of contents provided on the last page of this report.

General product information and considerations:

Syringe pump is a drug-injection equipment, which is intended for applications requiring accurate administration dosage, stable flow rate, low dose rate or long-time constant dose rate. The syringe pump is widely used in injection treatment of diseases, such as for children, patients with heart disease, chemotherapy of cancer, treatment in ICU, patients with diabetes, and so on.

IEC 60601-1-8：2006			
Clause	Requirement – Test	Result	Verdict
4	**GENERAL REQUIREMENTS**		
	ME EQUIPMENT or SYSTEM includes an ALARM SYSTEM complying with this collateral standard as a means of RISK CONTROL to have ME EQUIPMENT or SYSTEM notify the OPERATOR of a HAZARDOUS SITUATION		P
	RISK ASSESSMENT has also taken into consideration HAZARDS to PATIENTS, OPERATORS, and other persons arising from ALARM SYSTEM ... :	See RISK MANAGEMENT FILE	P
5	**ME EQUIPMENT IDENTIFICATION MARKING AND DOCUMENTS**		
5.1	Indicator lights and controls		P
	6.3.2.2 applied in addition to requirements for colours of indicator lights and their meanings in 7.8.1 of general standard		P
5.2	ACCOMPANYING DOCUMENTS		P
5.2.1	Instructions for use provide and indicate the following:		P
	- an overview of ALARM SYSTEM, including a listing and description of every possible ALARM CONDITION and a summary of how it is determined		P
	- any delay inherent in determination of an ALARM CONDITION		N/A
	- OPERATOR'S POSITION, and how and when to verify functionality of ALARM SYSTEM		P
	Instructions for use caution against setting ALARM LIMITS to extreme values that can render the ALARM SYSTEM useless		N/A

IEC 60601-1-8：2006			
Clause	Requirement – Test	Result	Verdict
6	**ALARM SYSTEMS**		
6.1.1	Grouping of ALARM CONDITIONS into PHYSIOLOGICAL, TECHNICAL or other ALARM CONDITIONS disclosed in instructions for use		P
6.1.2	ALARM CONDITIONS assigned to one or more of the following priorities: HIGH PRIORITY, MEDIUM PRIORITY, or LOW PRIORITY .....:		P
	Assignment of priorities is part of RISK MANAGEMENT PROCESS and is based on Table 1, except when a particular ALARM CONDITION priority is specified in a relevant particular standard .....:	See RISK MANAGEMENT FILE	P
	Priority of each ALARM CONDITION is disclosed in instructions for use, and priorities are, optionally, identified in groups		P
6.2	An INTELLIGENT ALARM SYSTEM is provided, and the instructions for use include an overview of how the ALARM SYSTEM accomplishes the following:	Not an intelligent alarm system	N/A
	a) determines an ALARM CONDITION on the basis of time, weightings, multiple variables, or other advance processing		N/A
	b) generates ALARM SIGNALS for two or more alarm conditions of equal priority		N/A
	c) changes the previously-assigned priority or relative prioritization of a particular ALARM CONDITION		N/A
	d) changes the ALARM SIGNAL GENERATION DELAY or ALARM CONDITION DELAY		N/A
	e) changes characteristics of the generated ALARM SIGNALS		N/A
6.3.1	Each ALARM CONDITION causes generation of visual ALARM SIGNALS		P
	RISK ASSESSMENT indicates the intended use environment requires additional auditory, verbal, vibratory ALARM SIGNALS, or ALARM SIGNALS produced by other means .....:	See RISK MANAGEMENT FILE	P

IEC 60601-1-8：2006			
Clause	Requirement – Test	Result	Verdict
6.3.2.1	ALARM SYSTEMS generate visual ALARM SIGNALS to indicate presence of ALARM CONDITIONS, their priority and each specific ALARM CONDITION		P
6.3.2.2	At least one visual indicator provided for OPERATOR to identify the equipment or part of the equipment that requires OPERATOR response or awareness		P
	a) ALARM SIGNAL indicates priority of the highest priority ALARM CONDITION		P
	b) ALARM SIGNAL can be perceived correctly at a distance of 4 m from the ALARM SYSTEM		P
	Alarm indicator lights, graphical simulations of indicator lights, or indications generated by some other type of visual display or device comply with the colour and flashing requirements of Table 2		P
	ALARM SYSTEMS not containing HIGH or MEDIUM PRIORITY ALARM CONDITIONS with visual indications that cannot be confused with a HIGH or MEDIUM PRIORITY alarm indicator light complying with Table 2 exempted from this requirement		N/A
	At least one visual ALARM SIGNAL is provided identifying specific ALARM CONDITION and its priority		P
	Signal is perceived correctly at a distance of 1 m from equipment or part of the equipment or from OPERATOR'S POSITION		P
	Text of visual indication placed next to an indicator light or on a display		P
	Presence of an ALARM CONDITION marked with symbol 1 of Table C.1 (i.e., symbol IEC 60417-5307: 2002-10)		P
	Priority indicated by addition of one, two, or three optional elements		P
	Each individual ALARM CONDITION is visually indicated, automatically, or by OPERATOR action when multiple ALARM CONDITIONS occur at the same time, except when:		P

IEC 60601-1-8：2006			
Clause	Requirement – Test	Result	Verdict
	An INTELLIGENT ALARM SYSTEM is provided preventing a lower internal rank ALARM CONDITION from generating ALARM SIGNALS when a higher internal rank ALARM CONDITION is generating or has recently generated ALARM SIGNALS		N/A
	Visual INFORMATION SIGNALS correctly perceived as different from visual ALARM SIGNALS at a distance of 1 m from ALARM SYSTEM or from OPERATOR'S POSITION under following conditions:		P
	– an OPERATOR with a visual acuity of 0 on the log MAR [17] scale or 6-6 (20/20) vision (corrected when necessary),		P
	– view-point at the OPERATOR'S POSITION or at any point within the base of a cone subtended by an angle of 30° to the axis horizontal to or normal to the centre of the plane of display of the monitoring display or visual indication, and		P
	– the ambient illuminance in the range [21] of 100 lx to 1500 lx		P
6.3.3	Auditory ALARM SIGNALS		P
6.3.3.1	a) ALARM SYSTEM with auditory ALARM SIGNALS has at least one set of priority encoded ALARM SIGNALS meeting requirements of Table 3 and 4, or		P
	b) one set of priority encoded ALARM SIGNALS generated by means of different technology and is VALIDATED		P
	ALARM SYSTEM additionally provided with other sets of auditory ALARM SIGNALS complies with the following:	No other sets of auditory alarm system	N/A
	c) auditory ALARM SIGNALS are priority encoded		N/A
	d) HIGH PRIORITY auditory ALARM SIGNALS of a particular set of ALARM SIGNALS convey a higher level of urgency than MEDIUM or LOW PRIORITY ALARM SIGNALS and INFORMATION SIGNALS of that ALARM SIGNAL set		N/A

IEC 60601-1-8：2006			
Clause	Requirement – Test	Result	Verdict
	e) MEDIUM PRIORITY auditory ALARM SIGNALS of a particular set of ALARM SIGNALS convey a higher level of urgency than the LOW PRIORITY ALARM SIGNALS and INFORMATION SIGNALS of that ALARM SIGNAL set		N/A
	f) auditory ALARM SIGNALS validated by clinical or simulated clinical usability testing		N/A
	g) means provided to store a set of auditory ALARM SIGNALS in the DEFAULT ALARM PRESET		N/A
	h) means provided to, optionally, store a set of auditory ALARM SIGNALS in ALARM PRESETS		N/A
	All melodies preclude possibility of confusion with auditory ALARM SIGNALS of Tables 3 and 4 and Annex F		P
	An ALARM SYSTEM generating an auditory ALARM SIGNAL not complying with the above requirements permitted when a TECHNICAL ALARM CONDITION precluding generation of the usual ALARM SIGNALS occurred		N/A
	Means provided to prevent the OPERATOR from unauthorized access to changing the auditory ALARM SIGNAL set in use		P
6.3.3.2	Measured auditory ALARM SIGNAL sound pressure range disclosed in instructions for use		P
	Sound pressure level of MEDIUM PRIORITY ALARM SIGNALS does not exceed that of HIGH PRIORITY ALARM SIGNALS.....:	No medium priority alarm	N/A
	Sound pressure level of LOW PRIORITY ALARM SIGNALS does not exceed that of MEDIUM PRIORITY ALARM SIGNALS.....:	No low priority alarm	N/A
	Auditory INFORMATION SIGNALS are distinguishable from those of auditory ALARM SIGNALS and their characteristics are disclosed in instructions for use	No auditory information signals	N/A
6.3.4	RISKS associated with verbal ALARM SIGNALS addressed in RISK MANAGEMENT PROCESS when applicable .....:	No verbal alarm signals	N/A

IEC 60601-1-8：2006			
Clause	Requirement – Test	Result	Verdict
6.4	Disclosure of delays		N/A
6.4.1	Sum of the maximum ALARM CONDITION DELAY plus the maximum ALARM SIGNAL GENERATION DELAY is greater than 10 s, and the statistics of each distribution or of the distribution of the sum are disclosed in instructions for use.....:		N/A
	Each delay or sum of delays disclosed in the instructions for use when the sum of the mean ALARM CONDITION DELAY plus the mean ALARM SIGNAL GENERATION DELAY is greater than 5 s ....:		N/A
6.4.2	ALARM SYSTEM provided with a means to send or receive ALARM CONDITIONS in a DISTRIBUTED ALARM SYSTEM, and instruction for use disclose:	Not a distributed alarm system	N/A
	a) delay time from onset of ALARM CONDITION to the point where representation of ALARM CONDITION leaves the SIGNAL OUTPUT PART		N/A
	b) maximum remote ALARM SIGNAL GENERATION DELAY or time to determine generation of TECHNICAL ALARM CONDITION		N/A
	For DISTRIBUTED ALARM SYSTEM, the ALARM SIGNAL GENERATION DELAY measured and reported as follows:		N/A
	c) from the onset of ALARM CONDITION		N/A
	d) from the time of local ALARM SIGNAL generation		N/A
	e) to or from the point presentation of the ALARM CONDITION leaves the SIGNAL INPUT/OUTPUT PART		N/A
	f) to or from the point that the presentation of ALARM CONDITION arrives at the SIGNAL INPUT/OUTPUT PART, or		N/A
	g) to the time of the remote ALARM SIGNAL generation		N/A

IEC 60601-1-8：2006			
Clause	Requirement – Test	Result	Verdict
6.5.1	ALARM PRESET using mechanical adjustment exempted from requirements of this sub-clause		P
	ALARM SYSTEM in NORMAL USE exempted from this sub-clause as it was capable of only retaining current ALARMS SETTINGS, it was not otherwise provided with ALARM PRESETS, and it displayed each adjustable ALARM SETTINGS continuously		P
	ALARM PRESETS include the ALARM LIMIT used to trigger each ALARM CONDITION and its priority		P
	ALARM PRESETS are determined from information available to the ALARM SYSTEM concerning the current PATIENT		P
	ALARM PRESETS include other parameters affecting or modify performance of the ALARM SYSTEM		P
	Instructions for use contain a warning statement to the effect that a potential hazard can exist if different ALARM PRESETS are used for the same or similar equipment in any single area		P
6.5.2	ALARM SYSTEM provided with at least one manufacturer-configured ALARM PRESET		P
	ALARM LIMITS and a summary of any algorithms used in any manufacturer-configured ALARM PRESETS disclosed in instructions for use		P
6.5.3.1	a) means provided on the ALARM SYSTEM that can store only one ALARM PRESET to prevent the OPERATOR from saving changes to this ALARM PRESET		P
	Saving changes to this ALARM PRESET restricted to RESPONSIBLE ORGANIZATION, and		P
	b) means provided to RESPONSIBLE ORGANIZATION for restoring ALARM PRESET to its manufacturer-configured state		P

IEC 60601-1-8：2006			
Clause	Requirement – Test	Result	Verdict
6.5.3.2	ALARM SYSTEM provided with means to store or activate one or more RESPONSIBLE ORGANIZATION -configured or OPERATOR-configured ALARM PRESETS in addition to any manufacturer-configured ALARM PRESETS includes the following features:		N/A
	a) means for the OPERATOR to choose between available ALARM PRESETS		N/A
	b) means for the OPERATOR to readily identify ALARM PRESET in use		N/A
	c) a warning statement in instructions for use to the effect that the OPERATOR should check to ensure current ALARM PRESET is appropriate prior to use on each PATIENT		N/A
	d) means for configuration and storage of ALARM PRESETS disclosed in ACCOMPANYING DOCUMENTS		N/A
	e) means to prevent the OPERATOR from saving changes to any RESPONSIBLE ORGANIZATION -configured or manufacturer-configured ALARM PRESET		N/A
	Saving changes to any RESPONSIBLE ORGANIZATION -configured or manufacturer-configured ALARM PRESET restricted to the RESPONSIBLE ORGANIZATION		N/A
	f) means to prevent the OPERATOR from saving changes to ALARM PRESETS stored by any other OPERATOR; and		N/A
	g) ALARM SYSTEM stores the current ALARM SETTINGS for later recall		N/A
6.5.4.1	DEFAULT ALARM PRESET capable of being set to values differing from manufacturer-configured values includes the following features:		P
	a) means to prevent any OPERATOR from storing changes to DEFAULT ALARM PRESET		P
	Storing changes to DEFAULT ALARM PRESET is restricted to RESPONSIBLE ORGANIZATION, and		P

IEC 60601-1-8：2006			
Clause	Requirement – Test	Result	Verdict
	b) means to the RESPONSIBLE ORGANIZATION to restore the DEFAULT ALARM PRESET to its manufacturer-configured values		P
6.5.4.2	Following features provided when condition a), b), c), or d) of this sub-clause exists:		P
	DEFAULT ALARM PRESET is automatically selected (prevailing condition).....:		P
	Means for the OPERATOR to select an ALARM PRESET (prevailing condition).....:		P
	Means for the OPERATOR to select the retained ALARM SETTINGS from previous use (prevailing condition).....:		N/A
	Instructions for use include an estimate of duration of power interruption after which ALARM SYSTEM is unable to restore the ALARM SETTINGS and the subsequent behaviour of the ALARM SYSTEM		P
6.5.5	ALARM SETTINGS are restored automatically after power is interrupted for ≤ 30 s, and this behaviour included in instructions for use		P
6.6.1	ALARM LIMIT consisted of a non-adjustable, a simple OPERATOR-adjustable set-point, or an algorithmically determined criterion.....:		P
6.6.2.1	ALARM LIMIT indicated continuously or by OPERATOR action when OPERATOR-adjustable ALARM LIMIT is provided		P
6.6.2.2	ALARM LIMIT is automatically set to ranges or percentages above or below the following value or setting .....:	Not automatically set	N/A
	a) value of a monitored variable at a point in time,		N/A
	b) recent values of a monitored variable, or		N/A
	c) a current control setting		N/A
	The ALARM LIMIT value is indicated continuously or by OPERATOR action, except when:		N/A

IEC 60601-1-8：2006			
Clause	Requirement – Test	Result	Verdict
	d) this ALARM LIMIT is obvious from the associated control setting and the behaviour is described in instructions for use, or		N/A
	e) this ALARM LIMIT is determined by an INTELLIGENT ALARM SYSTEM		N/A
6.6.2.3	During adjustment of any ALARM LIMIT or OPERATOR-adjustable ALARM PRESET, ALARM SYSTEM continued to operate normally		P
6.7	Means of restricting access to changing or to the storage of changes described in the technical description		P
6.8.1	Means provided for the OPERATOR to inactivate the auditory, or audiovisual and, generation of ALARM SIGNALS		P
	Inactivation of the generation of ALARM SIGNALS is, optionally, indefinite (i.e., ALARM or AUDIO OFF), or timed (i.e., ALARM or AUDIO PAUSED)		P
	Means provided to, optionally, inactivate generation of other ALARM SIGNALS		P
	Inactivation applies to an individual ALARM CONDITION, a group of ALARM CONDITIONS, entire ALARM SYSTEM, or parts of a DISTRIBUTED ALARM SYSTEM		P
	Flashing visual ALARM SIGNALS (6.3.2.2), optionally, inactivated by AUDIO PAUSED or AUDIO OFF		N/A
	When an ALARM SIGNAL inactivation applies to an individual ALARM CONDITION or a group of ALARM CONDITIONS, generation of ALARM SIGNALS from other ALARM CONDITIONS is unaffected		P
6.8.2	When ALARM SYSTEM is provided with a REMINDER SIGNAL, following requirements are met:	No reminder signal	N/A
	a) nature of the REMINDER SIGNAL and intervals between REMINDER SIGNALS disclosed in instructions for use,		N/A
	b) only RESPONSIBLE ORGANIZATION is provided with a means to disable the REMINDER SIGNAL, and		N/A

IEC 60601-1-8：2006			
Clause	Requirement – Test	Result	Verdict
	– to configure the maximum REMINDER SIGNAL interval, when adjustment is provided		N/A
	c) only the RESPONSIBLE ORGANIZATION is, optionally, provided with a means to permit designated OPERATORS to enable and disable the REMINDER SIGNAL		N/A
	– to permit any OPERATOR to enable and disable the REMINDER SIGNAL		N/A
6.8.3	When deemed acceptable by RISK ASSESSMENT of the intended use environment of ALARM SYSTEM, a global ALARM OFF or AUDIO OFF is, optionally, provided with the following features:		N/A
	a) a REMINDER SIGNAL, and		N/A
	b) means to configure (enable or disable) any global ALARM OFF or AUDIO OFF and restricted for use only by RESPONSIBLE ORGANIZATION to prevent the clinical OPERATOR from changing the configuration in NORMAL USE		N/A
6.8.4	Means provided for OPERATOR to terminate any ALARM SIGNAL inactivation state		P
	ALARM SIGNAL inactivation state, optionally, terminates automatically when the ALARM CONDITION generating an ALARM SIGNAL ceases upon entering this state		P
	When an ALARM SIGNAL inactivation state is terminated, ALARM SIGNALS of any current ALARM CONDITION cause the re-generation of ALARM SIGNALS		P
6.8.5	The ALARM SIGNAL inactivation states AUDIO PAUSED, ALARM PAUSED, AUDIO OFF, and ALARM OFF are visually indicated (marked) with the appropriate symbol in Table 5		P
	Indication is legible at a distance of 1 m from equipment, part of equipment, or from OPERATOR'S POSITION		P

IEC 60601-1-8：2006			
Clause	Requirement – Test	Result	Verdict
	Means of control used to enter one of the ALARM SIGNAL inactivation states is, optionally, marked with a symbol referenced in Table 5, and initiates the associated ALARM SIGNAL inactivation state		P
	Duration of AUDIO PAUSED or ALARM PAUSED disclosed in instructions for use		P
	The AUDIO PAUSED or ALARM PAUSED interval is OPERATOR adjustable and means to adjust the maximum interval is provided only to RESPONSIBLE ORGANIZATION		P
	Means are, optionally, provided for the OPERATOR to adjust the AUDIO PAUSED or ALARM PAUSED interval up to the maximum interval		N/A
6.9	Means of ALARM RESET are, optionally, marked with symbol IEC 60417-5309 (DB-2002-10) (symbol 2 of Table C.1) or marking 5 of Table C.2		N/A
6.10	A NON-LATCHING ALARM SIGNAL automatically ceases when its triggering event no longer exists		P
	A LATCHING ALARM SIGNAL continues to be generated after its triggering event no longer exists		N/A
	The ALARM SYSTEM consists of a mixture of LATCHING ALARM SIGNALS and NON-LATCHING ALARM SIGNALS		N/A
	When the ALARM CONDITION is of short duration, a MEDIUM PRIORITY auditory ALARM SIGNAL completes at least one full BURST and a HIGH PRIORITY auditory ALARM SIGNAL completes one half of one full BURST, except when inactivated by the OPERATOR		P
	Auditory ALARM SIGNALS cease when:		P
	a) an OPERATOR has initiated the AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF state, or		P
	b) an OPERATOR has ALARM RESET the ALARM CONDITION		P

IEC 60601-1-8：2006			
Clause	Requirement – Test	Result	Verdict
	Means are provided to prevent the OPERATORS from selecting between LATCHING and NON-LATCHING ALARM SIGNALS		N/A
	Selection between LATCHING and NON-LATCHING ALARM SIGNALS is restricted to RESPONSIBLE ORGANIZATION		N/A
6.11.1	Details necessary for use of a DISTRIBUTED ALARM SYSTEM disclosed in the technical description		N/A
	ALARM SYSTEM sends and receives data, including indication of INFORMATION SIGNALS and ALARM CONDITIONS, to or from other parts of DISTRIBUTED ALARM SYSTEM		N/A
	DISTRIBUTED ALARM SYSTEM is located outside of PATIENT ENVIRONMENT		N/A
	Part(s) of DISTRIBUTED ALARM SYSTEM are located outside of PATIENT ENVIRONMENT		N/A
	Data are transmitted between different parts of DISTRIBUTED ALARM SYSTEM by wire, telemetry or other means		N/A
6.11.2.1	In the DISTRIBUTED ALARM SYSTEM, means are provided to identify source of remote ALARM CONDITION at every site of ALARM SIGNAL generation	Not distributed alarm system	N/A
6.11.2.2	a) failure of communications or any remote part of DISTRIBUTED ALARM SYSTEM does not adversely affect any part of DISTRIBUTED ALARM SYSTEM other than loss of distributed functionality, and		N/A
	b) creates a TECHNICAL ALARM CONDITION in affected parts of DISTRIBUTED ALARM SYSTEM that can generate ALARM SIGNALS, or DISTRIBUTED ALARM SYSTEM is marked with a warning to the effect that it is not relied upon for receipt of ALARM SIGNALS		N/A

IEC 60601-1-8：2006			
Clause	Requirement – Test	Result	Verdict
6.12	ALARM SYSTEM provided with a log of occurrence of ALARM CONDITIONS	No log	N/A
	a) ALARM SYSTEM logs occurrence and identity of HIGH PRIORITY ALARM CONDITIONS		N/A
	b) instructions for use indicate whether the log is maintained when the ALARM SYSTEM is powered down; and		N/A
	c) instructions for use indicate what happens to the contents of the log after the ALARM SYSTEM has experienced a total loss of power for a finite duration		N/A

6.3.3.2	**TABLE: measurements of volume of auditory alarm signals and information signals**	P
Location of the microphone……..:		

ALARM CONDITION (1)	Measured sound pressure level (dB)	A-weighted background level (2) (dB)	Remarks
HIGH PRIORITY	68	24	P

Test Equipment
H1990-01-02 Exact sound level meter M2006-06-04 oscilloscope N92-02-01Electronical stopwatch

Test Report Photo

Photos and Explanations

Figure 1 The whole view

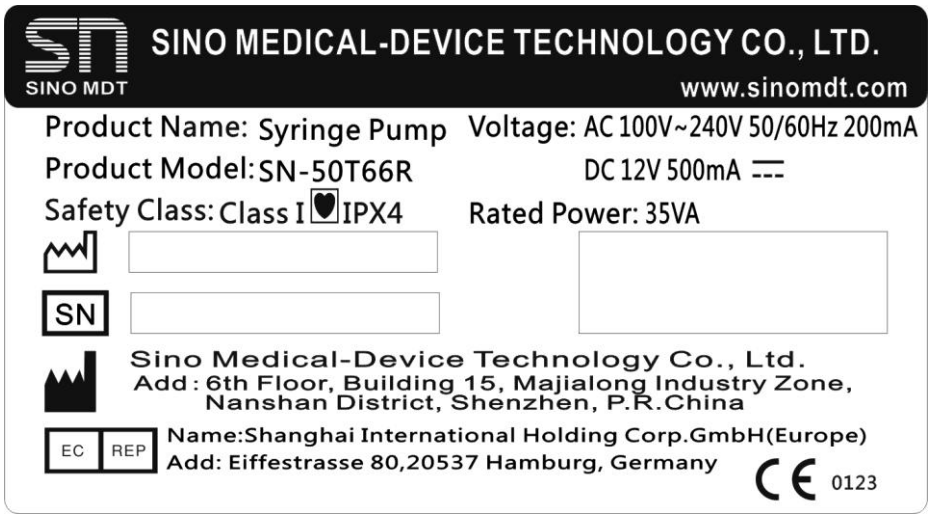

Figure 2 The label

Test Report Photo

Photos and Explanations

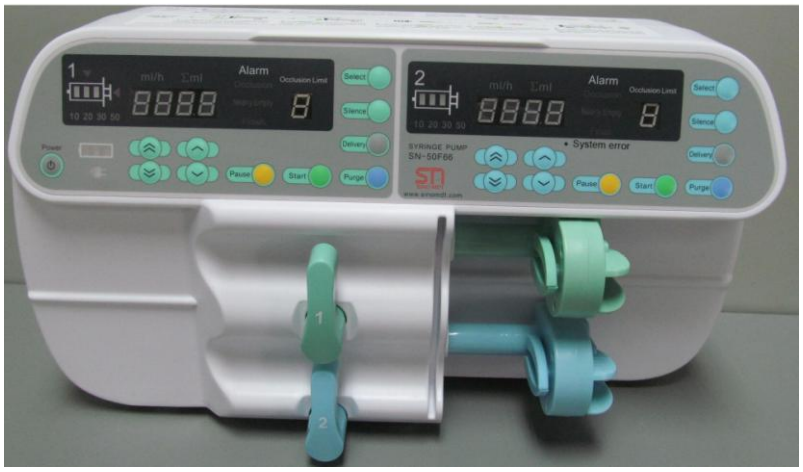

Figure 3 SN-50F66 Syringe Pump

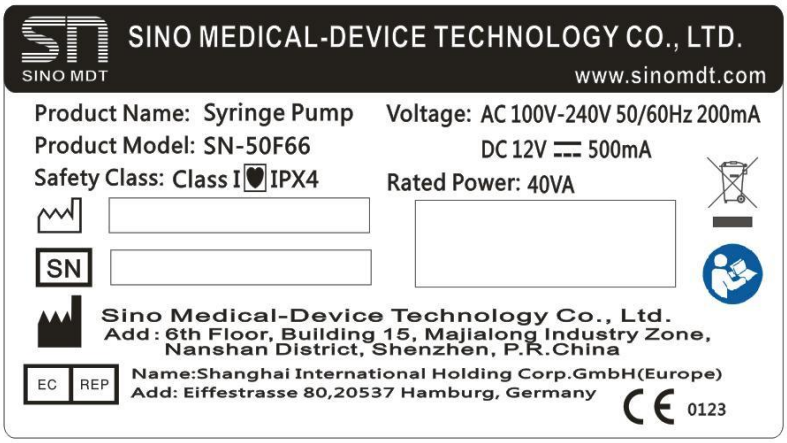

Figure 4 The label of SN-50F66 Syringe Pump

Test Report Photo

Photos and Explanations

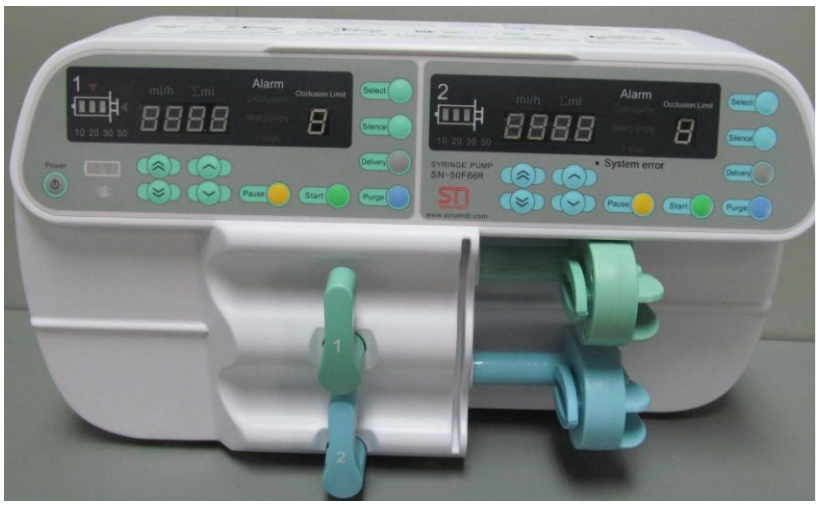

Figure 5 SN-50F66R Syringe Pump

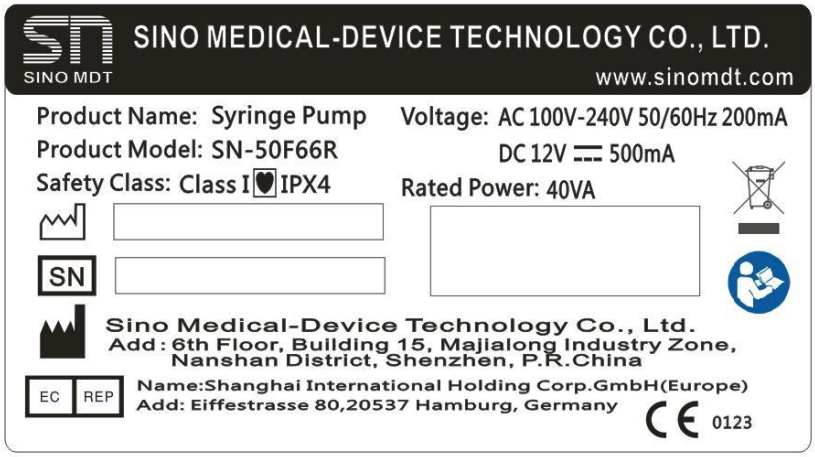

Figure 6 The label of SN-50F66R Syringe Pump

Test Report Photo

Photos and Explanations

Figure7 SN-50T66 Syringe Pump

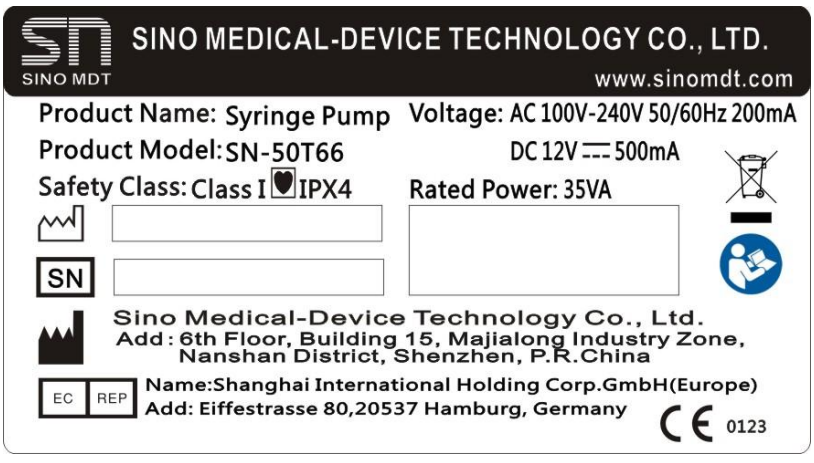

Figure 8 The label of SN-50T66 Syringe Pump

Test Report Photo

Photos and Explanations

Figure 9 SN-50C66 Syringe Pump

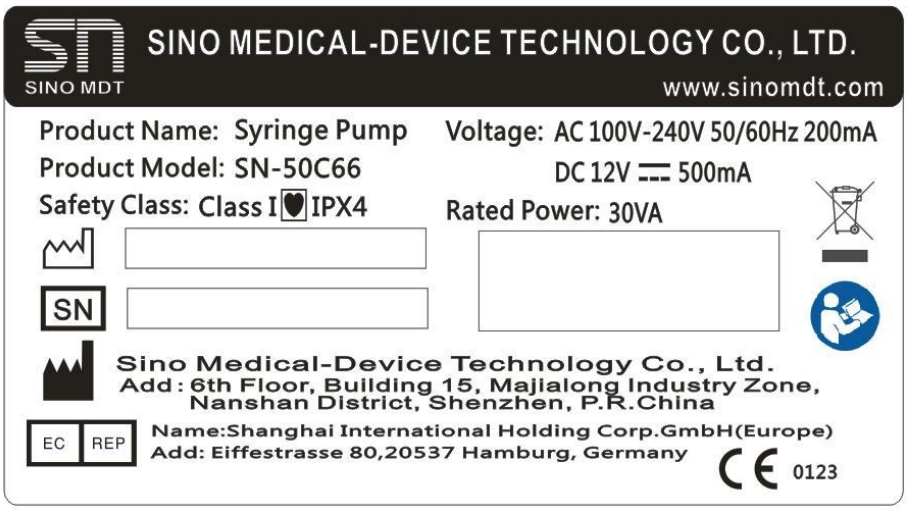

Figure 10 The label of SN-50C66 Syringe Pump

Test Report Photo

Photos and Explanations

Figure 11 SN-50C66R Syringe Pump

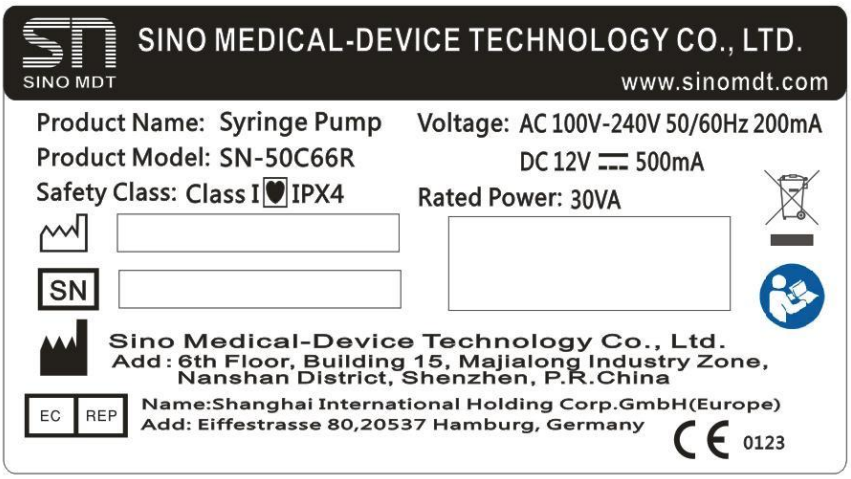

Figure 12 The label of SN-50C66R Syringe Pump

Test Report Photo

Photos and Explanations

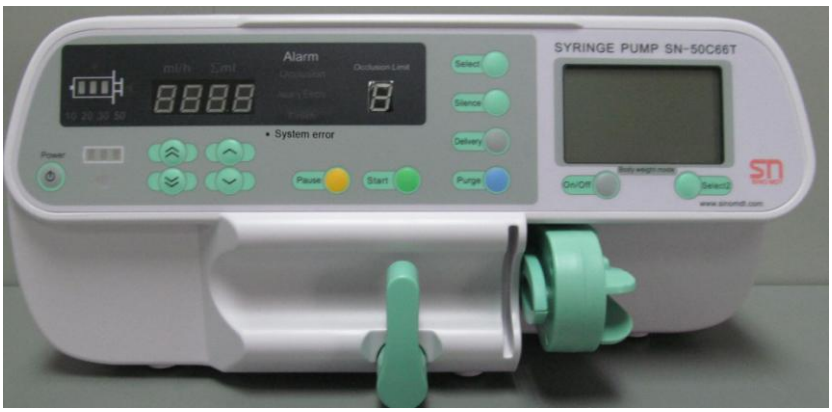

Figure 13 SN-50C66T Syringe Pump

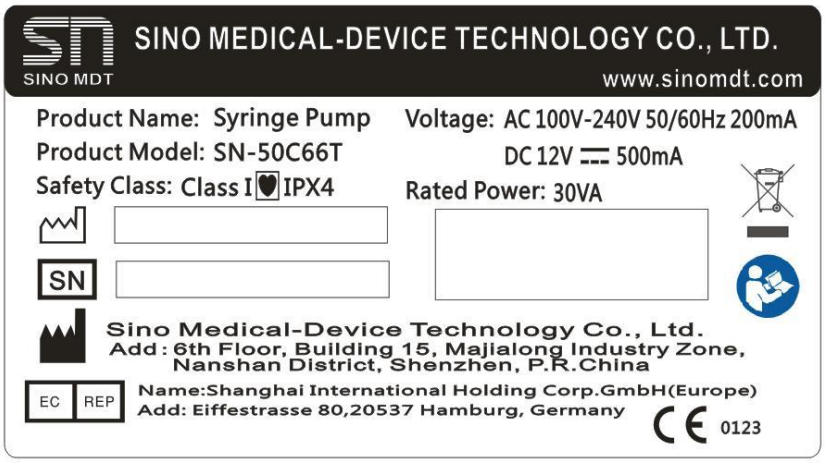

Figure 14 The label of SN-50C66T Syringe Pump

Test Report Photo

Photos and Explanations

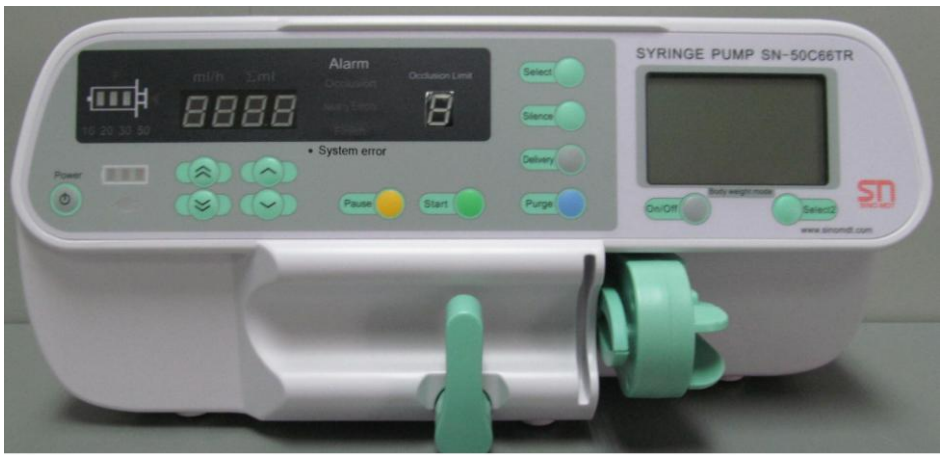

Figure 15 SN-50C66TR Syringe Pump

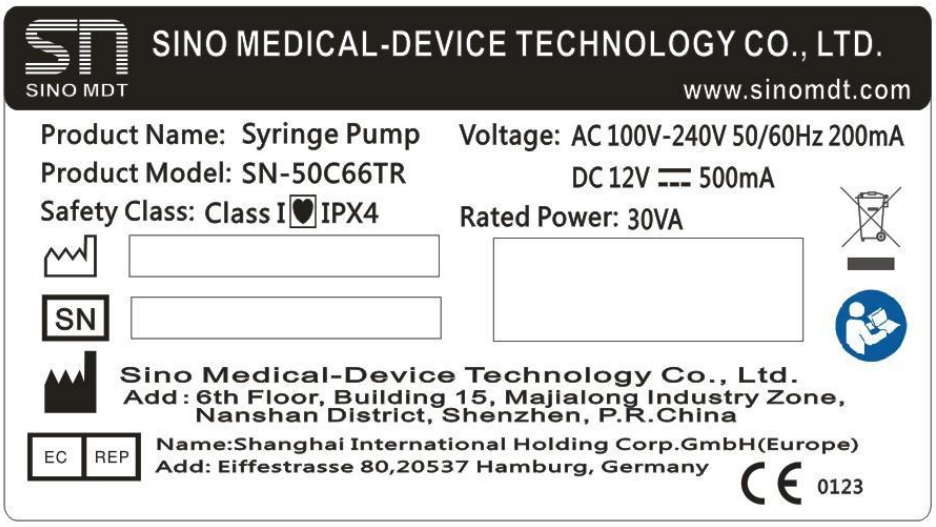

Figure 16 The label of SN-50C66TR Syringe Pump

Guangzhou Medical Instruments Quality Surveillance and Inspection Center of State Food and Drug Administration

Test Report Addendum

Samples' Descriptions
Syringe Pump is a series of products with high injection accuracy and stable flow rate, developed by Sino Medical-Device Technology Co., Ltd. It's composed of motor & actuator, lead screw, pusher head and syringe clamping device.
Types and Specifications or Other Explanations
By information and sample inspecting, the type SN-50F66、SN-50F66R、SN-50T66、SN-50C66、SN-50C66R、SN-50C66T、SN-50C66TR and SN-50T66R are in accord in principle, structure of circuit, they differ only in appearance and some auxiliary functions. So the type SN-50T66R can cover the type SN-50F66、SN-50F66R、SN-50T66、SN-50C66、SN-50C66R、SN-50C66T、SN-50C66TR.