

Technical Requirements for 96-Channel Automated Nucleic Acid Extractor

Product Number: EX-9601

Performance

1. Number of Channels: 96 channels.
2. Heating Module: Heating for lysis position and elution position (ambient temperature to 100°C).
3. Accuracy and Fluctuation of Reaction Zone Temperature Control: Temperature accuracy shall be within $\pm 0.5^{\circ}\text{C}$ of the set value, and temperature fluctuation shall not exceed 0.5°C .
4. Sample Volume: 20 μL – 1100 μL .
5. Plate Type: 96-well deep well plate.
6. Stirring and Mixing: 8 adjustable speed gears for user setting.
7. Equipped with UV disinfection lamp and lighting lamp.
8. Rear exhaust fan equipped.
9. Operating temperature: 10 – 40°C.
10. Operating relative humidity: 10 – 90% (non-condensing).
11. Power supply: AC 100 – 240 V, 45 – 65 Hz.
12. Overall dimension (Depth $\times$ Width $\times$ Height): 500 mm $\times$ 800 mm $\times$ 500 mm.
13. Weight: less than 60 kg.

Main Functions

1. The instrument can automatically complete nucleic acid extraction tasks through human-machine interactive instructions input by users;
2. The instrument shall have self-test function.
3. Fault prompt: The instrument shall give corresponding prompts for operation errors, mechanical faults and circuit faults.
4. Two standard USB expansion interfaces, supporting mouse and keyboard connection.
5. 10.1-inch touch display screen.
6. Built-in industrial control computer with Windows 10 operating system.
7. The number of editable and storable user programs shall be more than 500.

Appearance

1. The appearance shall be clean and tidy without cracks or scratches; texts and marks shall be clear;
2. Moving parts of the analysis system shall run smoothly without jamming or sudden jumping;
3. Fasteners shall be firmly connected without looseness.

Environmental Tests

The instrument shall meet the requirements of Group I climatic environmental tests and Group I mechanical environmental tests specified in GB/T 14710-2009.

Environmental test requirements shall comply with Group I climatic environmental tests and Group II mechanical environmental tests of GB/T 14710-2009, see Table for details.

Test Item	Test Requirements				
	Temp/Humidity	Duration	Recovery Time	Power-On Status	Test Condition
Rated Low	10°C	1	-	Powered On	-

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Temperature Operating Test					
Low Temperature Storage Test	-20°C	4	4	-	Reference Test Condition
Rated High Temperature Operating Test	30°C	1	-	Powered On	-
Continuous Operation Test	30°C	4	-	Powered On	-
High Temperature Storage Test	55°C	4	4	-	Reference Test Condition
Rated Humid Heat Operating Test	30°C / 70±3% RH	4	-	Powered On	-
Humid Heat Storage Test	40°C / 93±3% RH	48	2	-	Reference Test Condition
Vibration Test	-	-	-	-	Reference Test Condition
Shock Test	-	-	-	-	Reference Test Condition
Transportation Test	-	-	-	-	Reference Test Condition

Test Item	Detection Items				
				Power Supply Voltage	
	Initial Test	Intermediate Test	Final Test	198V	242V
Rated Low Temperature Operating Test	-	-			
Low Temperature Storage Test	-	-			
Rated High Temperature Operating Test	-	2.3.3			
Continuous Operation Test	-	-			
High Temperature Storage Test	-	-		-	-
Rated Humid Heat Operating Test	-	-		-	-
Humid Heat Storage Test	-	-		-	-
Vibration Test	-	-		-	-
Shock Test	-	-		-	-

Transportation Test	-	-		-	-
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Note: The temperature for low temperature storage test is -20°C (restricted by the storage conditions of photomultiplier tubes).

Safety Requirements: Shall comply with applicable clauses of GB 4793.1, GB 4793.6, GB 4793.9 and YY 0648.

Electromagnetic Compatibility Requirement shall comply with applicable clauses of GB/T 18268.1 and GB/T 18268.26.

Test Methods

1. Normal Operating Environmental Conditions

- 1.1. Power supply voltage: 220 V $\pm$ 22 V; 50 Hz $\pm$ 1 Hz
- 1.2. Ambient temperature: 10 °C – 30 °C
- 1.3. Relative humidity: 30% – 70%
- 1.4. Atmospheric pressure: 85.0 kPa – 106.0 kPa
- 1.5. Keep away from strong magnetic interference
- 1.6. Avoid direct strong light irradiation
- 1.7. Equipped with reliable grounding environment.

2. Main Functions of the Instrument

Verify by operating in accordance with the operation manual.

3. Appearance

Visual inspection, results shall conform to the provisions of Clause 2.7.

4. Environmental Test

Conduct tests in accordance with methods specified in GB/T 14710, test results shall meet the requirements of Clause 2.8.

5. Safety Test

Test in accordance with methods specified in GB 4793.1, GB 4793.6, GB 4793.9 and YY 0648, test results shall meet the requirements of Clause 2.9.

6. Electromagnetic Compatibility Test

Test in accordance with methods specified in GB/T 18268.1 and GB/T 18268.26, test results shall comply with the provisions of Clause 4.10.

7. Labels, Marks and Instructions for Use

Shall comply with the requirements of GB/T 29791.3.

8. Packaging, Transportation and Storage

8.1. Packaging

Packaging of the analyzer shall meet the following provisions:

Graphic symbols on packaging shall conform to GB/T 191;

Packaging shall protect the analyzer from natural and mechanical damage;

Operation manual shall be attached inside the packaging box.

8.2. Transportation

Transport in accordance with the manufacturer's specified requirements.

8.3. Storage

Store in accordance with the manufacturer's specified requirements.

Appendix A (Normative Appendix)

Features

1. This product is a desktop testing device.
2. This product adopts single-phase AC power supply of 220 V $\pm$ 22 V, 50 Hz $\pm$ 1 Hz with protective earthing.
3. Input power of this product: 450 VA.
4. This product is ordinary equipment without liquid ingress protection.
5. This product is non-explosion-proof and shall not be used in environments containing flammable, explosive or anesthetic gases.

Tests

1. Single-Fault Condition Tests (GB 4793.1-2007 Clause 4.4)

1.1. General (GB 4793.1-2007 Clause 4.4.1)

1.2. Application of Fault Conditions (GB 4793.1-2007 Clause 4.4.2)

1.2.1. Protective Impedance (GB 4793.1-2007 Clause 4.4.2.1)

Not applicable.

1.2.2. Protective Conductor (GB 4793.1-2007 Clause 4.4.2.2)

Requirement: The protective conductor shall be disconnectable, except for permanently connected equipment or equipment using connectors complying with GB/T 11918 ~ GB/T 11919.

Test Method: Implement the above requirements.

1.2.3. Equipment or Components with Short-Time or Intermittent Operation (GB 4793.1-2007 Clause 4.4.2.3)

Not applicable.

1.2.4. Motors (GB 4793.1-2007 Clause 4.4.2.4)

Requirement: Motors shall be either stalled or prevented from starting under full excitation; the more adverse condition shall be selected.

Test Method: Implement the above requirements.

1.2.5. Capacitors (GB 4793.1-2007 Clause 4.4.2.5)

Not applicable.

1.2.6. Power Transformers (GB 4793.1-2007 Clause 4.4.2.6)

Not applicable.

1.2.7. Output Circuits (GB 4793.1-2007 Clause 4.4.2.7)

Not applicable.

1.2.8. Equipment Supplied by More Than One Type of Power Source (GB 4793.1-2007 Clause 4.4.2.8)

Not applicable.

1.2.9. Cooling System (GB 4793.1-2007 Clause 4.4.2.9)

Not applicable.

1.2.10. Heating Devices (GB 4793.1-2007 Clause 4.4.2.10)

Not applicable.

1.2.11. Insulation Between Circuits and Components (GB 4793.1-2007 Clause 4.4.2.11)

Requirement: Insulation between circuits and components with values lower than those specified for basic insulation shall be short-circuited to test the prevention of flame spread.

Test Method: Implement the above requirements.

1.2.12. Interlocks (GB 4793.1-2007 Clause 4.4.2.12)

Not applicable.

1.2.13. Incorrect Voltage Selection (YY 0648-2008 Clause 4.4.2.101)

Not applicable.

2. Marks and Documents

2.1. Marks (GB 4793.1-2007 Clause 5.1)**2.1.1. General (GB 4793.1-2007 and YY 0648-2008 Clause 5.1.1)**

Requirement: The equipment shall be marked with marks complying with Clauses 5.1.2 to 5.2 of GB 4793.1-2007.

Except for marks on internal components, these marks shall be visible from the outside; or if covers or doors are intended to be removed or opened by operators without tools, the marks shall be visible after removal or opening.

Marks applicable to the whole equipment shall not be affixed to parts removable by operators without tools.

Letter symbols for quantities and units shall comply with IEC 60027; internationally recognized symbols including those in Table 1 of GB 4793.1-2007 shall be used wherever possible. If additional symbols are required, they shall not be confused with internationally recognized symbols. No color requirements apply to symbols except Symbol 101 specified in YY 0648-2008 Table 1. Graphic symbols shall be explained in accompanying documents.

Test Method: Verify by visual inspection.

2.1.2. Identification Markings (GB 4793.1-2007 and YY 0648-2008 Clause 5.1.2)

Requirement: The equipment shall at least bear the following markings:

Name or trademark of the manufacturer or supplier;

Model or name or other means of identifying the equipment. If the same model number is produced at multiple manufacturing sites, markings shall identify each production site.

Note: Manufacturing site identification may use codes and does not need to be marked externally on the equipment.

The equipment shall at least carry the following information:

Manufacturer's name or trademark and address (including city and country at minimum);

Model, name or other equipment identifier.

The following additional information shall be marked on the equipment, packaging or instruction manual:

Serial number format: 0303XXXXXPPPP, where XXXXX = serial number, PPPP = last two digits of production year in reverse order. Example: Instrument serial No.1 produced in 2016 shall be marked as 0303000011620.

The following content shall be provided:

Clear indication that the equipment is an in vitro diagnostic medical device;

Expiry date of consumables expressed in year, month, day sequence (if applicable).

Test Method: Verify by visual inspection.

2.1.3. Power Supply Markings (GB 4793.1-2007 Clause 5.1.3)

Requirement: The equipment shall be marked with the following power supply information:

Nature of power supply: AC: Rated frequency or frequency range;

Rated supply voltage or voltage range;

Maximum rated power (W) or apparent power (VA), or maximum rated input current when all accessories and modules are connected. If multiple voltage ranges are applicable, values shall be marked for each range, unless the difference between maximum and minimum values does not exceed 20% of the average value.

Test Method: Verify by visual inspection and measurement of power or input current after current stabilizes (normally 1 min later). The equipment shall operate under maximum power consumption state; transient values shall be ignored. Measured values shall not exceed marked values by more than 10%.

2.1.4. Fuse Markings (GB 4793.1-2007 Clause 5.1.4)

Requirement: Any fuse replaceable by operators shall be marked adjacent to the fuse holder to identify the correct replacement fuse.

Test Method: Verify by visual inspection.

2.1.5. Terminals, Connectors and Operating Controls (GB 4793.1-2007 Clause 5.1.5)

Requirement: Terminals, connectors, controls and indicators (including fluid inlets/outlets for gas, water and discharge) shall be marked to indicate their purpose if safety is relevant. Symbol 14 from GB 4793.1-2007 Table 1 may be used if space is limited.

Test Method: Implement the above requirements.

Terminals (GB 4793.1-2007 Clause 5.1.5.1)

Requirement: Mains supply terminals shall be identifiable. The following terminals shall be marked as specified:

Protective conductor terminals shall be marked with Symbol 6 from GB 4793.1-2007 Table 1, except when integrated into an approved mains appliance inlet connector. The symbol shall be affixed adjacent to or on the terminal.

Test Method: Verify by visual inspection.

Measurement Circuit Terminals (GB 4793.1-2007 Clause 5.1.5.2)

Not applicable.

2.1.6. Switches and Circuit-Breakers (GB 4793.1-2007 Clause 5.1.6)

Requirement: If power switches or circuit breakers serve as disconnecting devices, their ON and OFF positions shall be clearly marked. Symbols 9 and 10 from GB 4793.1-2007 Table 1 may be used in appropriate cases. Indicator lamps alone are not deemed compliant. Symbols 9 and 10 shall not be used for switches other than mains power switches.

Test Method: Verify by visual inspection.

2.1.7. Equipment Protected by Double or Reinforced Insulation (GB 4793.1-2007 Clause 5.1.7)

Requirement: Symbol 11 from GB 4793.1-2007 Table 1 shall not be affixed to equipment only partially protected by double or reinforced insulation.

Test Method: Verify by visual inspection.

2.1.8. Field Wiring Terminal Boxes (GB 4793.1-2007 Clause 5.1.8)

Not applicable.

2.1.9. Transportation and Storage Markings (YY 0648-2008 Clause 5.1.101)

Requirement: Labels indicating special transportation and storage conditions shall be affixed to packaging.

Test Method: Verify by visual inspection.

2.2. Warning Marks (GB 4793.1-2007 and YY 0648-2008 Clause 5.2)

Requirement: Warning marks shall be visible when the equipment is ready for normal use. If a warning applies to a specific part, it shall be marked on or adjacent to that part.

Warning mark dimensional requirements:

Symbol height ≥ 2.75 mm; text height ≥ 1.5 mm with color contrast against the background.

If operators or responsible persons need to consult documentation to maintain equipment protection, Symbol 14 from GB 4793.1-2007 Table 1 shall be affixed to the equipment. Symbol 14 does not require accompanying explanatory symbols in the manual.

Equipment with potential infectious risks from samples or reagents shall be clearly marked with Symbol 101 from YY 0648-2008 Table 1.

Equipment with hazards from chemical substances shall carry appropriate hazard symbols or Symbol 14 if dedicated symbols are unavailable.

Containers or bags holding biohazard waste removable during normal operation shall bear Symbol 101 from YY 0648-2008 Table 1.

Test Method: Verify by visual inspection.

2.3. Mark Durability (GB 4793.1-2007 and YY 0648-2008 Clause 5.3)

Requirement: Marks specified in Clauses A2.1.2 ~ A2.2 shall be permanently affixed and remain legible under normal use, resistant to temperature, friction, solvents and disinfectants specified by the manufacturer.

Test Method: Visually inspect after durability test: wipe external marks with cloth dampened with specified cleaning agent (or isopropanol if unspecified) for 30 s with moderate hand pressure. After wiping, marks shall remain clear without peeling or curling.

2.4. Documentation (GB 4793.1-2007 Clause 5.4)

2.4.1. General (GB 4793.1-2007 and YY 0648-2008 Clause 5.4.1)

Requirement: Documentation supplied with the equipment for safety purposes shall contain the following:

Intended use of the equipment;

Technical specifications;

Operating instructions;

Name and address of manufacturer or supplier providing technical support;

Information specified in Clauses A2.4.2 ~ A2.4.5.

Warning statements and explanations for symbols marked on the equipment shall be provided in the manual or permanently legible on the equipment. In particular, text explaining potential hazards and required countermeasures shall be provided wherever Symbol 14 is affixed.

Information shall be provided for any risks that cannot be reduced to acceptable levels by protective measures defined in this standard. Training requirements or personal protective equipment shall be specified if needed to mitigate risks to acceptable limits.

Test Method: Visual inspection of supplied documentation.

2.4.2. Equipment Ratings (GB 4793.1-2007 Clause 5.4.2)

Requirement: Supplied documentation shall include:

Mains voltage/range, frequency/range, power or current rating;

Statement of environmental operating range designed for the equipment.

Test Method: Verify by visual inspection.

2.4.3. Transportation, Installation and Assembly Instructions (YY 0648-2008 Clause 5.4.3)

Requirement: Documentation for responsible personnel shall contain:

Post-delivery transportation instructions;

Positioning and installation instructions including ventilation and clearance required for safe operator maintenance;

Assembly instructions;

Protective earthing instructions;

Instructions for handling, containment and discharge of hazardous substances including backflow prevention requirements;

Drainage requirements for equipment discharging biohazardous, chemical or hot liquids;

Detailed protective measures against hazardous radiation;

Mains connection instructions.

Test Method: Verify by reviewing operation manual.

2.4.4. Equipment Operation Manual (YY 0648-2008 Clause 5.4.4)

Requirement: Operation manual shall include:

Detailed description of all operating controls and operating sequences for all operation modes;

Warning not to place the equipment where disconnecting devices are inaccessible;

Instructions for connecting accessories and external equipment including details of compatible attachments, detachable parts and special consumables;

Explanation of all symbols marked on the equipment and reasons for their use in hazardous zones;

Operator-permissible actions in case of equipment faults;

Cleaning and disinfection instructions with recommended materials;

Waste disposal instructions;

Training and PPE requirements if normal operation involves hazardous materials handling;

Mandatory protective gloves or other barriers when handling potentially infectious human specimens or reagents with skin contact risk;

Statement that equipment protection may be compromised if operated outside manufacturer-specified procedures.

Test Method: Verify by reviewing operation manual.

2.4.5. Self-Testing IVD Equipment (YY 0648-2008 Clause 5.4.4.101)

Not applicable.

2.4.6. Equipment Maintenance Instructions (GB 4793.1-2007 Clause 5.4.5)

Requirement: Sufficiently detailed preventive maintenance and inspection instructions shall be provided for safety-related tasks performed by responsible personnel. Inspection and replacement procedures shall be specified for hoses or liquid-containing components whose failure could create hazards. Components requiring exclusive inspection or service by the manufacturer or authorized agents shall be identified.

Test Method: Verify by reviewing maintenance documentation.

2.4.7. Equipment Decommissioning, Transport and Disposal Instructions (YY 0648-2008 Clause 5.4.101)

Requirement: Instructions shall be provided to mitigate hazards during equipment shutdown, transportation or disposal, including biohazard minimization requirements.

Test Method: Verify by reviewing documentation.

2.4.8. Transportation and Storage Specifications (YY 0648-2008 Clause 5.4.102)

Requirement: Manufacturer-specified transportation and storage environmental ranges shall be documented and reproduced on outer packaging.

Test Method: Verify by visual inspection of packaging and manual.

3. Protection Against Electric Shock (GB 4793.1-2007 Clause 6)**3.1. General (GB 4793.1-2007 Clause 6.1)****3.1.1. Requirement (GB 4793.1-2007 Clause 6.1.1)**

Requirement: The equipment shall provide protection against electric shock under normal and single-fault conditions; accessible parts shall not become dangerously live.

Test Method: Conduct testing per GB 4793.1-2007 Clause 6.1.1.

3.1.2. Exceptions (GB 4793.1-2007 Clause 6.1.2)

Not applicable.

3.2. Determination of Accessible Parts (GB 4793.1-2007 Clause 6.2)**3.3. Permissible Limits for Accessible Parts (GB 4793.1-2007 Clause 6.3)**

Requirement: Voltage, current, charge or energy between any accessible part and reference test earth, or between any two accessible parts within 1.8 m surface/air distance on the same equipment, shall not exceed normal condition limits (A3.3.1) or single-fault condition limits (A3.3.2).

Test Method: Test per GB 4793.1-2007 Clause 6.3.

3.3.1. Normal Condition Limits (GB 4793.1-2007 Clause 6.3.1)

Requirement: Conditions are deemed dangerously live if values exceed: AC rms 33 V / peak 46.7 V; DC 70 V.

Test Method: Verify per specified limits.

3.3.2. Single-Fault Condition Limits (GB 4793.1-2007 Clause 6.3.2)

Requirement: Conditions are deemed dangerously live if values exceed: AC rms 55 V / peak 78 V; DC 140 V.

Test Method: Verify per specified limits.

3.4. Protection Under Normal Operating Conditions (GB 4793.1-2007 Clause 6.4)

Requirement: One or more of the following protection measures shall be implemented:

Basic insulation;

Enclosures or baffles;

Protective impedance.

Enclosures and baffles shall meet rigidity requirements of GB 4793.1-2007 Clause 8.1. Insulated enclosures/baffles shall comply with basic insulation criteria.

Clearances and creepage distances between accessible and live components shall satisfy basic insulation requirements of GB 4793.1-2007 Clause 6.7.

Solid insulation separating live and accessible parts shall withstand basic insulation voltage test specified in GB 4793.1-2007 Clause 6.8.

Test Method: Test per GB 4793.1-2007 Clause 6.4.

3.5. Protection Under Single-Fault Conditions (GB 4793.1-2007 Clause 6.5)

Requirement: Supplementary protection shall be provided via one or more measures specified in Clauses A3.5.1 ~ A3.5.3, or automatic power cut-off upon fault occurrence, to prevent accessible parts from becoming live under single-fault conditions.

Test Method: Test per GB 4793.1-2007 Clause 6.5.

3.5.1. Protective Bonding (GB 4793.1-2007 Clause 6.5.1)

Requirement: If primary protection (Clause A3.4) fails and accessible conductive parts become live, such parts shall be bonded to protective earth terminals or isolated by conductive shielding connected to protective earth.

Test Method: Test per GB 4793.1-2007 Clause 6.5.1.

Integrity of Protective Bonding (GB 4793.1-2007 Clause 6.5.1.1)

Requirement:

Protective bonding shall be formed by structural members or independent conductors, capable of withstanding thermal and electrodynamic stress until overcurrent protection disconnects mains supply as specified in GB 4793.1-2007 Clause 9.5.

Partial equipment removable by operators shall not break protective bonding, unless the removable section carries the main power inlet connection.

Protective conductors may be bare or insulated with green-yellow sheath, with exceptions:

Earthing braids may be green-yellow or transparent;

Internal protective conductors, ribbon cables, busbars and flexible printed circuits may use any color if misidentification risk is absent. Green-yellow combination shall exclusively identify protective conductors.

Equipment with protective bonding shall be fitted with terminals compatible with protective conductor connection per A3.5.1.2.

Test Method: Verify by visual inspection.

Protective Conductor Terminals (GB 4793.1-2007 Clause 6.5.1.2)

Requirement:

Contact surfaces shall be metallic;

Integrated protective earth terminals of appliance inlet connectors are deemed compliant;

Protective earth terminals shall be adjacent to mains terminals for detachable cord and permanently connected equipment;

Current-carrying capacity of protective earth terminals shall match or exceed mains supply terminals;

Plug-in connector assemblies combining protective earth and supply circuits shall establish protective bonding first and disconnect supply conductors last during mating/unmating;

Earth screw terminals shall have minimum thread engagement of 3 full turns with thread size $\geq$ M4; contact pressure shall not degrade via material deformation.

Test Method: Verify by visual inspection.

Protective Bond Impedance for Plug-In Equipment (GB 4793.1-2007 Clause 6.5.1.3)

Requirement: Impedance between socket protective earth terminal and all accessible bonded parts shall not exceed 0.1 Ω (power cord impedance excluded).

Test Method: Measure per specified limit.

Protective Bond Impedance for Permanently Connected Equipment (GB 4793.1-2007 Clause 6.5.1.4)

Not applicable.

Indirect Protective Bond for Test and Measurement Equipment (GB 4793.1-2007 Clause 6.5.1.5)

Not applicable.

3.5.2. Double and Reinforced Insulation (GB 4793.1-2007 Clause 6.5.2)

Requirement: Clearances and creepage distances for double/reinforced insulation assemblies shall meet applicable

requirements of GB 4793.1-2007 Clause 6.7 (Appendix D). Enclosures shall comply with GB 4793.1-2007 Clause 6.9.2. Solid reinforced insulation shall withstand reinforced insulation voltage test of GB 4793.1-2007 Clause 6.8.
Test Method: Test per GB 4793.1-2007 Clause 6.5.2.

3.5.3. Protective Impedance (GB 4793.1-2007 Clause 6.5.3)

Not applicable.

3.5.4. Automatic Power Disconnection (GB 4793.1-2007 Clause 6.5.4)

Not applicable.

3.6. Connection to External Circuits (GB 4793.1-2007 Clause 6.6)

Not applicable.

3.7. Clearances and Creepage Distances (GB 4793.1-2007 Clause 6.7)**3.7.1. General Clearance Requirements (GB 4793.1-2007 Clause 6.7.3.1)**

Requirement (per GB 4793.1-2007 Table 5 for mains circuits):

Basic insulation clearance ≥ 1.5 mm;

Reinforced insulation clearance ≥ 3.0 mm.

Test Method: Visual inspection and dimensional measurement.

3.7.2. Creepage Distance Values (GB 4793.1-2007 Clause 6.7.3.3)

Requirement (per GB 4793.1-2007 Table 7):

Basic insulation creepage distance ≥ 3.0 mm;

Reinforced insulation creepage distance ≥ 6.0 mm.

Test Method: Visual inspection and dimensional measurement.

3.8. Dielectric Strength Test Procedures (GB 4793.1-2007 Clause 6.8)**3.8.1. Reference Test Earth (GB 4793.1-2007 Clause 6.8.1)**

Requirement: Reference test earth consists of interconnected components including:

Any protective or functional earth terminals;

All accessible conductive parts excluding live parts complying with A3.3.1 limits; live parts complying with A3.3.1 shall be connected together but excluded from reference earth;

Metallic foil wrapped around all accessible insulating enclosure surfaces (max 20 mm distance from terminals for test voltage $\leq$ AC/DC 10 kV; greater separation for higher voltages to prevent flashover);

Soft conductive material wrapped around insulated operating controls.

Test Method: Follow specified setup requirements.

3.8.2. Humidity Preconditioning (GB 4793.1-2007 Clause 6.8.2)

Requirement: Precondition equipment before dielectric testing to ensure safety under humid operating conditions; equipment shall be unpowered during preconditioning. Remove manually detachable covers/components for simultaneous conditioning if foil wrapping is required post-recovery.

Preconditioning parameters: Humidity chamber maintained at 92.5% $\pm$ 2.5% RH, air temperature 40°C $\pm$ 2°C.

Equipment stabilized at 42°C $\pm$ 2°C for minimum 4 h before humidification. Air circulation inside chamber; no condensed water dripping onto equipment. Conditioning duration: 48 h. Post-conditioning recovery: 2 h under reference test conditions with ventilation covers open.

Test Method: Follow preconditioning sequence.

3.8.3. Test Execution Rules (GB 4793.1-2007 Clause 6.8.3)

Requirement: Complete dielectric voltage test within 1 h after humidity recovery; equipment unpowered during testing. No voltage testing between interconnected/isolated circuits. Disconnect parallel protective impedance and voltage-limiting devices during testing. Split circuit testing if combined protective layers impose excessive test voltages on non-reinforced insulation components.

Test Method: Follow test execution rules.

3.8.4. Voltage Test Criteria (GB 4793.1-2007 Clause 6.8.4)

Requirement:

Basic insulation test: 50 Hz AC 1390 V applied for 5 s; no breakdown or repetitive flashover allowed; corona discharge disregarded. Voltage ramped smoothly within 5 s to target value.

Reinforced insulation test: 50 Hz AC 2230 V applied for 5 s; no breakdown or repetitive flashover allowed; corona discharge disregarded. Voltage ramped smoothly within 5 s to target value.

Test Method: Conduct voltage withstand test per above parameters.

3.9. Structural Requirements for Electric Shock Protection (GB 4793.1-2007 Clause 6.9)

3.9.1. General (GB 4793.1-2007 Clause 6.9.1)

Requirement: Loose wires, screws or detached components shall not render accessible parts live under fault conditions.

Test Method: Verify by visual inspection.

3.9.2. Enclosures for Double/Reinforced Insulated Equipment (GB 4793.1-2007 Clause 6.9.2)

Requirement: All-insulated enclosures shall satisfy double/reinforced insulation criteria. Metallic enclosures shall either:

Be internally lined with insulating coatings/baffles fully surrounding live components and any metallic surfaces that could contact live parts upon component detachment.

Test Method: Visual inspection, dimensional measurement and dielectric testing per A3.8.

3.9.3. Over-Range Indication (GB 4793.1-2007 Clause 6.9.3)

Not applicable.

3.10. Mains Supply and Internal Component Wiring (GB 4793.1-2007 Clause 6.10)

3.10.1. Mains Power Cables (GB 4793.1-2007 Clause 6.10.1)

Requirement: Applicable to fixed and detachable factory-supplied power cords:

a) Cable rating shall match equipment maximum operating current; cables shall comply with GB 5023 or GB 5013; certification by recognized testing bodies constitutes compliance proof.

b) Detachable cords and appliance inlet connectors shall withstand maximum temperature of either component.

c) Only green-yellow insulated conductors shall connect to protective earth terminals.

Test Method: Verify by visual inspection.

3.10.1. Fixed Power Cord Installation (GB 4793.1-2007 Clause 6.10.2)

Not applicable.

3.10.2. Plugs and Couplers (GB 4793.1-2007 Clause 6.10.3)

Requirement:

Mains plugs and appliance couplers shall comply with national plug/socket standards.

Plugs for low-voltage equipment (< limits specified in A3.3.2 a)) shall be incompatible with higher-voltage mains sockets; mains connectors shall not serve other circuit connections.

Pin terminals of corded equipment shall not retain dangerous charge 5 s after mains disconnection.

Test Method: Verify by visual inspection.

3.11. Mains Disconnection Means (GB 4793.1-2007 Clause 6.11)

3.11.1. General (GB 4793.1-2007 Clause 6.11.1)

Requirement: Disconnecting devices shall be fitted to isolate all live conductors from each energy supply source, except exceptions specified in A3.11.1.1. Functional switches are permitted alongside mandatory disconnect devices.

Test Method: Comply with GB 4793.1-2007 Clause 6.11.1.

Exceptions (GB 4793.1-2007 Clause 6.11.1)

Not applicable.

3.11.2. Equipment-Type Disconnect Requirements (GB 4793.1-2007 Clause 6.11.2)

Permanently Wired and Multiphase Equipment (GB 4793.1-2007 Clause 6.11.2.1)

Not applicable.

Single-Phase Corded Equipment (GB 4793.1-2007 Clause 6.11.2.2)

Requirement: Shall adopt one of the following disconnecting means:

Mains switch or circuit breaker;

Tool-free detachable appliance coupler;

Unlocked separable plug compatible with building wall sockets.

Test Method: Verify by visual inspection.

Functional Hazards from Disconnection (GB 4793.1-2007 Clause 6.11.2.3)

Not applicable.

3.11.3. Disconnect Device Specifications (GB 4793.1-2007 Clause 6.11.3)

Requirement: Disconnect switches/circuit breakers shall be positioned as close to mains inlet as possible; power-consuming components shall not be wired between supply inlet and disconnect device.

Test Method: Verify by visual inspection.

Switches and Circuit Breakers as Disconnect Devices (GB 4793.1-2007 Clause 6.11.3.1)

Requirement: Switches/circuit breakers serving as mains disconnect shall comply with GB 14048.1 and GB 14048.3. ON/OFF symbols 9 and 10 (GB 4793.1-2007 Table 1) shall be marked if only one disconnect device is fitted. **Mains switches shall not be integrated into power cords and shall not disconnect protective earth conductors.**

Test Method: Verify by visual inspection.

Appliance Couplers and Separable Plugs (GB 4793.1-2007 Clause 6.11.3.2)

Requirement: Couplers/plugs used as disconnect means shall be easily identifiable and accessible. Single-phase portable equipment with cord length ≤ 3 m is deemed to have accessible plugs. Protective earth contacts of appliance couplers shall mate before supply contacts and separate after supply contacts during disconnection.

Test Method: Verify by visual inspection.

4. Protection Against Mechanical Hazards (GB 4793.1-2007 Clause 7)**4.1. General (GB 4793.1-2007 Clause 7.1)**

Requirement: Normal and single-fault operation shall not create mechanical injury risks. All accessible enclosure edges, protrusions, corners, openings, baffles and handles shall be smooth to prevent injury during routine use.

Test Method: Comply with GB 4793.1-2007 Clause 7.1.

4.2. Moving Parts (GB 4793.1-2007 Clause 7.2)

Not applicable.

4.3. Stability (GB 4793.1-2007 Clause 7.3)

Requirement: Freestanding equipment (unfixed to building structures) shall remain stable during normal operation. Automatic stabilizing mechanisms or warning labels shall be fitted if drawers/extenders compromise stability when extended.

Compliance verified by the following tests (container filled with maximum adverse working load; castors positioned to worst-case orientation):

Tilt test: Tilt equipment 10° from horizontal plane in all directions (excluding handheld devices);

Vertical force test for equipment ≥ 1 m height and ≥ 25 kg mass, and all floor-standing units: Apply downward force of 250 N or 20% equipment weight (whichever smaller) to all upper surfaces (max 2 m height for tall equipment) in all horizontal directions (excluding upward); doors/drawers set to fully extended worst-case position;

Horizontal surface load test for floor-standing equipment: Apply downward 800 N force to all horizontal working surfaces and protruding surfaces below 1 m height at positions generating maximum overturning moment.

Equipment shall not tip during all stability tests.

Test Method: Visual inspection of stability warning markings.

4.4. Lifting and Handling Fixtures (GB 4793.1-2007 Clause 7.4)

Not applicable.

4.5. Wall-Mounted Equipment (GB 4793.1-2007 Clause 7.5)

Not applicable.

4.6. Ejected Components (GB 4793.1-2007 Clause 7.6)

Not applicable.

5. Resistance to Mechanical Shock and Impact (GB 4793.1-2007 Clause 8)

Requirement: Equipment shall possess sufficient mechanical strength and securely fixed components/electrical connections to avoid hazards from routine impact and collision. Conduct enclosure rigidity test (A5.1) for all equipment and drop test (A5.2) for non-fixed equipment; equipment unpowered during testing.

Post-test acceptance criteria:

No accessible dangerously live parts;

No hazardous enclosure cracks;

No clearance/creepage distance reduction below minimum values or damaged internal wiring insulation;

No damaged/loose baffles;

No exposed moving parts except exceptions in A4.2;

No damage enabling flame propagation.

Minor cosmetic dents, scratches and indentations that do not degrade insulation/clearance/creepage or liquid protection shall be disregarded; damage to non-enclosure components is disregarded.

Test Method: Conduct mechanical impact testing per standard clauses.

5.1. Enclosure Rigidity Test (GB 4793.1-2007 Clause 8.1)**5.1.1. Static Load Test (GB 4793.1-2007 Clause 8.1.1)**

Requirement: Secure equipment to rigid support surface; apply 30 N force via 12 mm diameter hemispherical hard probe to all accessible enclosure surfaces where deformation could create hazards (including portable equipment base). For non-metallic enclosures with high-temperature durability uncertainty, stabilize equipment at 40 °C or maximum rated operating temperature before testing and disconnect mains supply prior to force application.

Test Method: Conduct static rigidity load test per specification.

5.1.2. Dynamic Impact Test (GB 4793.1-2007 Clause 8.1.2)

Requirement: Tighten all operator-replaceable base/cover fasteners to normal service torque; secure equipment rigidly and apply dynamic impact to all accessible surfaces vulnerable to damage under routine handling.

Test Method: Conduct dynamic impact test per specification.

5.2. Drop Test (GB 4793.1-2007 Clause 8.2)**5.2.1. Non-Handheld Non-Plug-In Equipment (GB 4793.1-2007 Clause 8.2.1)****Corner Drop Test (GB 4793.1-2007 Clause 8.2.1.1)**

Requirement: Place equipment in normal operating position on smooth rigid concrete/steel surface; insert 10 mm wooden block under one base corner and 20 mm block under adjacent corner. Elevate the opposite corner to either 100 mm ±10 mm height or 30° tilt angle (whichever more adverse) and release free fall. Repeat sequentially for all four base edges, one drop per corner.

Test Method: Conduct four-corner free drop test per specification.

Flat Surface Drop Test (GB 4793.1-2007 Clause 8.2.1.2)

Not applicable.

5.2.2. Handheld and Direct Plug-In Equipment (GB 4793.1-2007 Clause 8.2.2)

Not applicable.

5.2.3. Transportation and Storage Impact (YY 0648-2008 Clause 8.101)

Requirement: Packaged equipment shall not create hazards after transportation/storage under manufacturer-specified conditions.

Test Method: Test per YY 0648-2008 Clause 8.101.

6. Flame Propagation Prevention (GB 4793.1-2007 Clause 9)

Requirement: Flames shall not propagate outside equipment under normal or single-fault conditions. Compliance verified via one or more of the following methods:

Single-fault flame propagation testing with acceptance criteria specified in GB 4793.1-2007 Clause 4.4.4.3;

Elimination/minimization of internal ignition sources per GB 4793.1-2007 Clause 9.1;

Flame containment design per GB 4793.1-2007 Clause 9.2.

Multiple verification methods may be applied per equipment hazard zones.

Test Method: Conduct flame safety verification per standard clauses.

6.1. Elimination or Reduction of Internal Ignition Sources (GB 4793.1-2007 Clause 9.1)

Not applicable.

6.2. Flame Containment Design (GB 4793.1-2007 Clause 9.2)

Requirement: Equipment meeting one of the structural criteria below is deemed compliant for flame propagation risk reduction:

Enclosure structure complies with A6.2.1 and satisfies GB 4793.1-2007 Clauses 9.4 b) or c).

Test Method: Comply with GB 4793.1-2007 Clause 9.2 testing procedures.

6.2.1. Structural Fire Safety Requirements (GB 4793.1-2007 Clause 9.2.1)

Requirement:

Insulated wiring shall achieve flammability rating FV-1 or superior per GB/T 11020. Connector and component insulation shall meet FV-2 or superior flammability class. Printed circuit board requirements specified in GB 4793.1-2007 Clause 14.8 apply. Compliance verified via material data sheets or FV flammability testing of three component samples (full assembly, thin-wall sections with vents, or standardized test coupons).

Enclosure criteria:

Bottom panels shall be solid or fitted with baffles within GB 4793.1-2007 Figure 7 limits, or constructed of metal with perforations complying with GB 4793.1-2007 Table 12, or metal mesh with maximum 2 mm mesh pitch and minimum 0.45 mm wire diameter;

No openings in side panels within shaded Zone C of GB 4793.1-2007 Figure 7;

Enclosures, baffles and fire barriers shall be metal (excluding magnesium) or non-metallic material rated FV-1 or superior per GB/T 11020;

Enclosures and fire baffles shall possess adequate structural rigidity.

Test Method: Verify enclosure fire safety construction per specification.

6.3. Energy-Limited Circuits (GB 4793.1-2007 Clause 9.3)

Not applicable.

6.4. Equipment Containing or Using Flammable Liquids (GB 4793.1-2007 Clause 9.4)

Not applicable.

6.5. Overcurrent Protection (GB 4793.1-2007 Clause 9.5)

Requirement: Mains-powered equipment shall be protected by fuses, circuit breakers, thermal cut-offs or impedance-limiting circuits to restrict fault energy input and mitigate fire/electric shock risks. Overcurrent devices shall not be fitted to protective earth conductors; single-pole fuses/breakers shall not be installed on neutral conductors of polyphase equipment.

Test Method: Verify use of CCC or CE certified power supply modules.

6.5.1. Permanently Connected Equipment Overcurrent Protection (GB 4793.1-2007 Clause 9.5.1)

Not applicable.

6.5.2. Corded Equipment Overcurrent Protection (GB 4793.1-2007 Clause 9.5.2)

Requirement: Overcurrent protection components shall be installed internally within equipment housing.

Test Method: Verify by visual inspection.

7. Temperature Limits and Heat Resistance (GB 4793.1-2007 Clause 10)

7.1. Surface Temperature Limits for Burn Prevention (GB 4793.1-2007 Clause 10.1)

Requirement: Touchable surface temperature shall not exceed 80 °C under normal operating conditions at 40 °C ambient or maximum rated operating temperature; maximum 105 °C permitted under single-fault conditions.

Test Method: Conduct surface temperature measurement per standard clause.

7.2. Winding Temperature Limits (GB 4793.1-2007 Clause 10.2)

Requirement: Winding insulation temperature shall not exceed values specified in GB 4793.1-2007 Table 10 under normal or single-fault conditions if overheating creates hazards.

Test Method: Verify via temperature measurement.

7.3. Other Temperature Measurement Requirements (GB 4793.1-2007 Clause 10.3)

Not applicable.

7.4. Temperature Test Execution Rules (GB 4793.1-2007 Clause 10.4)

Not applicable.

7.5. Heat Resistance Criteria (GB 4793.1-2007 Clause 10.5)**7.5.1. Thermal Stability of Clearances and Creepage Distances (GB 4793.1-2007 Clause 10.5.1)**

Requirement: Clearance and creepage distance values shall remain compliant with A3.7 under continuous operation at 40°C or maximum rated ambient temperature.

Test Method: Visual inspection and dimensional measurement post thermal conditioning.

7.5.2. Non-Metallic Enclosure Heat Resistance (GB 4793.1-2007 Clause 10.5.2)

Requirement: Non-metallic enclosures shall withstand high-temperature conditioning via one of two protocols:

Unpowered storage at 70°C ±2°C or 10°C above maximum measured operating temperature (whichever higher) for 7 h; empty enclosures may be conditioned separately if internal components risk thermal damage.

Powered operation at reference test ambient +20 °C for extended thermal soak.

Post-conditioning acceptance criteria: No accessible live components; pass enclosure rigidity test A5.1 and dielectric withstand test A3.8 (without humidity preconditioning) if suspected insulation degradation.

Test Method: Conduct thermal soak testing per specified protocol.

7.5.3. Insulation Material Heat Resistance (GB 4793.1-2007 Clause 10.5.3)

Requirement: Insulation supporting mains-connected components shall prevent flame propagation under short-circuit fault conditions.

Test Method: Test insulation heat resistance per standard clause.

8. Protection Against Liquid Hazards (GB 4793.1-2007 Clause 11)**8.1. General (GB 4793.1-2007 Clause 11.1)**

Requirement: Equipment processing or containing liquids shall be designed to protect operators and surrounding environment from liquid-related hazards during normal operation.

Test Method: Verify compliance via A8.2 and A8.3 testing sequences.

8.2. A8.2 Cleaning and Disinfection Compatibility (GB 4793.1-2007 Clause 11.2)

Requirement: Manufacturer-specified cleaning/disinfection procedures shall not create direct, electrical or corrosion-induced structural hazards. Verify by three cleaning cycles and one disinfection cycle per manual specifications.

If surface dampness is observed post-treatment, equipment shall pass dielectric withstand test A3.8 (no humidity preconditioning) and accessible part voltages shall remain below A3.3.1 limits.

Test Method: Conduct cleaning/disinfection compatibility testing.

8.3. Spilled Liquid Protection (YY 0648-2008 Clause 11.13)

Requirement: Equipment construction shall prevent live/uninsulated components or corrosive/toxic/flammable fluid contact from creating hazards if liquids spill during routine operation.

Test Method: Test per YY 0648-2008 Clause 11.13.

8.4. Liquid Overflow Protection (GB 4793.1-2007 Clause 11.4)

Not applicable.

8.5. Battery Electrolyte Hazards (GB 4793.1-2007 Clause 11.5)

Not applicable.

8.6. Special Liquid Protection Grades (GB 4793.1-2007 Clause 11.6)

Not applicable.

8.7. Liquid Pressure and Leakage Safety (GB 4793.1-2007 Clause 11.7)

Not applicable.

9. Protection Against Radiation, Acoustic and Ultrasonic Pressure (GB 4793.1-2007 Clause 12)**9.1. General Radiation Requirements (GB 4793.1-2007 Clause 12.1)**

Not applicable.

9.2. Ionizing Radiation Equipment (GB 4793.1-2007 Clause 12.2)**9.2.1. Ionizing X/Gamma Radiation (GB 4793.1-2007 Clause 12.2.1)**

Not applicable.

9.2.2. Accelerated Electron Radiation (GB 4793.1-2007 Clause 12.2.2)

Not applicable.

9.3. Ultraviolet Radiation Safety (GB 4793.1-2007 Clause 12.3)

Not applicable.

9.4. Microwave Radiation Safety (GB 4793.1-2007 Clause 12.4)

Not applicable.

9.5. Acoustic and Ultrasonic Pressure Limits (GB 4793.1-2007 Clause 12.5)**9.5.1. Sound Pressure Level Limits (GB 4793.1-2007 Clause 12.5.1)**

Not applicable.

9.5.2. Ultrasonic Pressure Hazards (GB 4793.1-2007 Clause 12.5.2)

Not applicable.

9.6. Laser Source Safety (GB 4793.1-2007 Clause 12.6)

Not applicable.

10. Protection Against Released Substances, Explosion and Implosion (YY 0648-2008 Clause 13)**10.1. Toxic and Hazardous Gas Emissions (GB 4793.1-2007 and YY 0648-2008 Clause 13.1)**

Not applicable.

10.2. Explosion and Implosion Prevention (GB 4793.1-2008 Clause 13.2)**10.2.1. Component Explosion Risks (GB 4793.1-2007 Clause 13.2.1)**

Not applicable.

10.2.2. Battery Charging Explosion Hazards (GB 4793.1-2007 Clause 13.2.2)

Not applicable.

10.2.3. Cathode Ray Tube Implosion (GB 4793.1-2007 Clause 13.2.3)

Not applicable.

10.2.4. High-Voltage Component Explosion Risks (GB 4793.1-2007 Clause 13.2.4)

Not applicable.

11. Components (GB 4793.1-2007 Clause 14)**11.1. General Component Safety Rules (GB 4793.1-2007 Clause 14.1)**

Requirement: Components relevant to safety shall operate within rated limits unless specific exceptions are documented.

Components shall comply with safety clauses of corresponding GB/IEC standards (other standard clauses optional).

Components certified by recognized third bodies against equivalent non-GB/IEC safety standards are also acceptable.

Equivalent tests already completed during component certification may be waived for full equipment testing.

Test Method: Verify component compliance per standard clause.

11.2. Motors (GB 4793.1-2007 Clause 14.2)**11.2.1. Motor Overheat Protection (GB 4793.1-2007 Clause 14.2.1)**

Requirement: Motors shall be fitted with thermal cut-offs or overheat protection if stall/prevented startup creates electric shock, overheating or fire hazards (per single-fault test A1.1.2.4).

Test Method: Test motor thermal protection compliance.

11.2.2. Series-Wound Motors (GB 4793.1-2007 Clause 14.2.2)

Not applicable.

11.3. Overheat Protection Devices (GB 4793.1-2007 and YY 0648-2008 Clause 14.3)

Not applicable.

11.4. Fuse Holders (GB 4793.1-2007 Clause 14.4)

Not applicable.

11.5. Mains Voltage Selectors (GB 4793.1-2007 Clause 14.5)

Not applicable.

11.6. High-Integrity Components (GB 4793.1-2007 Clause 14.6)

Not applicable.

11.7. External Test Power Transformers (GB 4793.1-2007 Clause 14.7)

Not applicable.

11.8. Printed Circuit Boards

Requirement: Printed circuit base materials shall achieve flammability rating FV-1 or superior per GB/T 11020. Exception: Flexible thin-film PCBs implementing energy-limited circuits defined in A6.3. Compliance verified via material datasheets or FV flammability testing of three representative PCB samples (full board, thin-wall vent sections, standardized test coupons).

Test Method: Verify PCB flammability rating.

11.9. Transient Overvoltage Limiting Circuits and Components (GB 4793.1-2007 Clause 14.9)

Not applicable.

12. Interlock-Based Protection (GB 4793.1-2007 Clause 15)

Not applicable.

13. Test and Measurement Equipment Special Provisions (GB 4793.1-2007 Clause 16)

Not applicable.

14. Inspection Rules**14.1. Inspection Items**

Factory Acceptance Test (FAT): A2.1.2, A2.1.3, A3.3, A3.5.1.3, A3.8.4

Type Test: All items specified in Appendix A

14.2. Sampling Quantity

Factory inspection: 100% unit-by-unit testing

Medical Device Registration Test: 1 unit submitted

Safety Certification Test: 1 unit submitted

14.3. Acceptance Judgment Criteria

Factory inspection: Single failed item renders unit non-conforming.

Registration & Periodic Type Test: Single non-conforming item permits component repair followed by agreed retest; re-failure after repair results in full rejection.

Safety Certification Test: Single non-conformity triggers double sampling (2 units total); failure of any item on duplicate samples results in full batch rejection.

Attachment 1 List of Cited Standards

1. GB/T 191-2008: Packaging Pictorial Marks.
2. GB 4793.1-2007: Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use Part 1: General Requirements.
3. YY 0648-2008: Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment.
4. GB/T 14710-2009: General Requirements and Test Methods for Medical Electrical Equipment Environmental Tests.
5. YY/T 0466.1-2009: Medical Devices Symbols to Be Used with Medical Device Labels, Marking and Information to Be Supplied Part 1: General Requirements.
6. GB/T 9969-2008: General Principles for Industrial Product Instruction Manuals.
7. GB 4793.9-2013: Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use Part 9: Particular Requirements for Laboratory Analytical Equipment.
8. GB/T 18268.1-2010: Electromagnetic Compatibility of Electrical Equipment for Measurement, Control and Laboratory Use Part 1: General Requirements.
9. GB/T 18268.26-2010: Electromagnetic Compatibility of Electrical Equipment for Measurement, Control and Laboratory Use Part 26: Particular Requirements for In Vitro Diagnostic (IVD) Medical Devices.
10. YY/T 1155-2009: Fully Automatic Chemiluminescence Immunoassay Analyzer.

Attachment 2 Factory Acceptance Test Rules**1. Inspection Items:**

- 1.1. Number of Channels
- 1.2. Heating Module
- 1.3. Accuracy and Fluctuation of Reaction Zone Temperature Control
- 1.4. Identification Markings (GB 4793.1-2007 and YY 0648-2008 Clause 5.1.2)
- 1.5. Power Supply Markings (GB 4793.1-2007 Clause 5.1.3)
- 1.6. Permissible Limits for Accessible Parts (GB 4793.1-2007 Clause 6.3)
- 1.7. Protective Bond Impedance for Plug-In Equipment (GB 4793.1-2007 Clause 6.5.1.3)
- 1.8. Voltage Test Criteria (GB 4793.1-2007 Clause 6.8.4)

2. Sampling Plan:

100% unit-by-unit factory inspection

3. Judgment Standard:

Any single non-compliant inspection item shall render the equipment unqualified.