

Test report:	No. 900466
Report date:	04.09.2026
Manufacturer:	Закрытое акционерное общество специальное конструкторское бюро «Хроматэк» Россия, 424000, Республика Марий Эл, город Йошкар-Ола, улица Строителей, дом 94
Name (trade mark/model/type/article) of the sample(s):	Medical equipment
Standard(s) establishing requirements and/or test methods, including amendments:	Technical Regulation of the Customs Union "On safety of low-voltage equipment" (TR CU 004/2011) Technical Regulation of the Customs Union "Electromagnetic compatibility of technical equipment" (TR CU 020/2011)
The test results stated in this report apply only to the submitted sample(s). Reproduction or reprinting of this test report without permission of the testing laboratory is not permitted.	

Test conditions:	
Ambient temperature, °C	20 ± 5
Relative humidity, %	30 ÷ 80
Atmospheric pressure, kPa	84 ÷ 115

Test results

TR CU 004/2011 On safety of low-voltage equipment

GOST 12.2.007.0-75

Clause	Requirement / test item	Assessment result
2	Classes of electrical products according to the method of protection against electric shock	-
2.1	Five protection classes are established: 0, 01, I, II, III.	Complies
3	Safety requirements for the electrical product and its parts	-
3.1	General requirements	-
3.1.1	Availability of noise and vibration protection measures.	Complies
3.1.2	Products creating electromagnetic fields shall have protective elements (screens, absorbers, etc.).	Not applicable
3.1.3	Limitation of harmful radiation (thermal, optical, X-ray, etc.) and indication of protective elements in technical specifications.	Not applicable
	Requirements for means limiting the intensity of radiation and ultrasound.	Not applicable
3.1.4	Availability of design elements providing protection against accidental contact with moving, live and heated parts.	Complies
3.1.5	Exclusion of accidental switching on and switching off.	Complies
3.1.6	Arrangement and connection of product parts shall ensure convenience and safety during assembly, inspection, testing and maintenance.	Complies
	Where necessary, products shall be equipped with inspection windows, hatches and local lighting facilities.	Complies
3.1.7	The product design shall prevent incorrect connection during installation.	Complies
	The design of plugs and socket-outlets for voltage above 42 V shall differ from the design of plugs and socket-outlets for voltage 42 V and below.	Complies
3.1.8	Where necessary, products shall be equipped with signalling devices, inscriptions and rating plates.	Complies
	For connection by means of a plug and socket-outlet, the power source shall be connected to the socket-outlet and the load to the plug.	Complies
	Warning signals, inscriptions and plates shall indicate energized condition, voltage presence, insulation breakdown, operating mode, prohibition of access inside without proper precautions, excessive temperature of parts, operation of protective devices, etc.	Complies

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	Signs used for warning plates and signalling shall comply with GOST 12.4.026 and be placed on products in locations convenient for viewing.	Complies
3.1.9	Availability of lifting, lowering and holding devices for installation works for products and components with mass exceeding 20 kg.	Not applicable
	Shape, dimensions and rated load capacity of lifting devices shall comply with GOST 4751-73 or GOST 13716-73. Other devices ensuring safe installation and rigging works are permitted.	Not applicable
3.1.10	Fire safety of the product and its elements shall be ensured both in normal and abnormal operating modes.	Complies
3.2	Requirements for insulation	-
Clause	Requirement / test item	Assessment result
3.2.1	Selection of insulation for the product and its parts is determined by heat-resistance class, supply voltage level and climatic environmental factors.	Complies
	Values of dielectric strength and insulation resistance shall be specified in standards and technical specifications for particular types of products.	Complies
	For products operating at voltage not higher than 12 V AC and 36 V DC, it is permitted not to state dielectric strength and insulation resistance values in the specified documents.	Not applicable
3.2.2	Insulation of accessible parts shall provide protection against electric shock.	Complies
	Coating of live parts with varnish, enamel or similar materials is not sufficient for protection against direct contact with such parts and against electric arc transfer from live parts to other metal parts.	Complies
3.3	Requirements for protective earthing	-
3.3.1	Availability of an earthing element on the equipment, except for equipment of protection classes II and III.	Complies
	Products which may be manufactured without an earthing element and need not be earthed.	Not applicable
3.3.2	Welded or threaded connections for connection of the earthing conductor.	Complies
	By agreement with the customer, the earthing conductor may be connected to the product by soldering or crimping performed with a special tool, fixture or machine.	Not applicable
3.3.3	Compliance of the earthing terminal with GOST 21130-75.	Complies
	Bolts, screws and studs used as fastening parts shall not be used for earthing.	Complies
3.3.4	The bolt (screw, stud) for connection of the earthing conductor shall be made of corrosion-resistant metal or coated with a metal protecting it from corrosion; the contact area shall have no surface paint.	Complies
3.3.5	The earthing bolt (screw, stud) shall be located on the product in a safe and convenient place for connection of the earthing conductor.	Complies

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	A permanent earthing symbol shall be placed near the point where the earthing conductor specified in clause 3.3.2 is to be connected.	Complies
	Dimensions of the symbol and method of application shall comply with GOST 21130-75 and, for luminaires, with GOST 17677-82.	Complies
	A contact area for connection of the earthing conductor shall be provided around the bolt (screw, stud). The area shall be protected against corrosion or made of corrosion-resistant metal and shall have no surface paint.	Complies
	Measures shall be taken to prevent loosening of contacts between the earthing conductor and earthing bolt (screw, stud), such as lock nuts or spring washers.	Complies
	Diameters of the bolt (screw, stud) and contact area.	Complies
3.3.6	Use of washers.	Complies
	The washer material shall meet the same requirements as the material of the earthing bolt (screw, stud).	Complies
3.3.7	Electrical connection shall be ensured between all accessible non-current-carrying metal parts which may become live and the earthing elements.	Complies
	Earthing resistance shall not exceed 0.1 Ohm.	Complies
3.3.8	Availability of an earthing element on enclosures, frames, racks, etc.	Complies
3.3.9	Independent connection of separate parts of the product to the earthing element.	Complies
Clause	Requirement / test item	Assessment result
3.3.10	Earthing of product parts installed on moving parts.	Complies
3.3.11	Location of the earthing element of the metal enclosure inside or outside the enclosure.	Complies
3.3.12	Electrical contact between removable and earthed parts of the equipment.	Not applicable
3.4	Requirements for control devices	-
3.4.1	Control devices shall be provided with inscriptions or symbols.	Complies
3.4.2	In automatic operating mode, manual controls shall be disabled.	Not applicable
3.4.3	Using manual controls in a sequence different from that specified shall not lead to a hazard.	Complies
	For products having several controls for the same operation from different stations, simultaneous control from different stations shall be prevented.	Not applicable
	Emergency stop buttons shall be made without the above interlock.	Complies
3.4.4	Products having several emergency stop buttons shall use latching buttons.	Not applicable

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	Buttons without forced return are permitted when acting on power elements that allow voltage to be supplied only after removal of manual locking.	Not applicable
3.4.5	Controls locked in a set position shall have a position indicator.	Complies
3.4.6	Metal shafts of manual drives and similar parts shall be insulated from live parts and shall have electrical contact with earthed parts.	Not applicable
3.4.7	Surface temperature of controls shall not exceed 40 °C.	Complies
	For equipment with internal temperature equal to or below 100 °C, surface temperature shall not exceed 35 °C. If these temperatures cannot be achieved for technical reasons, measures shall be provided to protect personnel from possible overheating.	Not applicable
3.4.8	The control used for stopping shall be red.	Complies
	The control used for starting (switching on) shall have achromatic colour (black, grey or white). It is permitted to make this control green.	Complies
	A control used alternately for stopping or starting the product shall be achromatic only. Handles of automatic circuit breakers may be yellow-brown.	Complies
	A control acting to prevent product failure shall be yellow.	Not applicable
	A control used for operations other than those listed above shall be achromatic or blue.	Not applicable
3.4.9	Increased size of the emergency stop button.	Complies
3.4.10-3.4.12	Working zones for installation of controls.	Complies
3.4.13-3.4.14	Installation height of measuring instruments.	Complies
3.4.10 – 3.4.15	Dimensions specified in clauses 3.4.10-3.4.14 may be adopted differently depending on product purpose and operating conditions.	Not applicable
3.4.15	Actuating force of pushbuttons shall not exceed the values specified in Table 2.	Complies
3.5	Requirements for interlocking	-
3.5.1	When interlocking is provided, false operation shall be prevented.	Not applicable
Clause	Requirement / test item	Assessment result
3.5.2	Interlocking of products intended for installation in rooms whose entrances are not interlocked and having holding electromagnets or charged springs shall be designed so as to eliminate hazards related to movement of product parts due to accidental removal or application of voltage to control circuits.	Not applicable
3.5.3	By agreement with the customer, instead of interlocks whose design significantly complicates maintenance of electrical products, other measures ensuring safe	Not

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	maintenance may be applied.	applicab le
3.6	Requirements for enclosures	-
3.6.1	Enclosures shall be connected with the main parts of products into a single structure, cover the hazardous area and be removable only with a tool.	Complies
3.6.2	Where necessary, enclosures shall have handles, brackets and other devices for convenient and safe holding during removal or installation.	Compli es
3.6.3	When doors and hatches of enclosures are opened or closed, contact with moving parts or live parts shall be prevented.	Complies
3.6.4	The degree of protection against contact with live and moving parts by means of enclosures shall comply with GOST 14254 and be specified in technical specifications for particular products.	Complies
3.6.5	Enclosures shall retain protective properties in normal and abnormal operating modes according to their marking or product documentation.	Complies
3.6.6	Enclosures of products containing contact connections should not be made of thermoplastic materials.	Compli es
3.7	Requirements for terminals and entry devices	-
3.7.1	Entry of wires into housings through insulating parts.	Compli es
3.7.2	Design and material of entry devices shall prevent accidental contact with live parts, as well as short-circuiting of conductors to the housing or between each other.	Complies
3.7.3	There shall be sufficient space inside the entry device for wire entry and termination.	Compli es
3.7.4	Screw contact connections shall not be a source of ignition in the "poor contact" mode.	Compli es
3.8	Requirements for warning signalling	-
3.8.1	Signalling shall be visual or audible.	Compli es
	Visual signalling may be provided by continuously lit or flashing lights.	Compli es
3.8.2	Application of colours.	Compli es
3.8.3	Signal lamps and other visual signalling devices shall have symbols or inscriptions indicating the meaning of signals.	Compli es
3.9	Requirements for marking and distinctive colouring	-
3.9.1	Plug connectors shall be marked to identify the parts of connectors to be connected to each other. Mating parts of the same connector shall have identical marking.	Complies
	Marking shall be applied on housings of mating connector parts in a visible place. Marking may be omitted if the connector of this type is the only one in the product.	Complies
3.9.2	Terminals of the product shall be marked. Hanging marking tags are not permitted.	Compli es
3.9.3	Conductor marking shall be applied at both ends of each conductor in accordance with regulatory and technical documentation.	Compli es
3.9.4	Conductor marking shall be made so that it remains on the marked conductor when the conductor is disconnected from the terminal.	Compli es

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3.9.5	Colour of conductor insulation according to functional purpose.	Complies
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Complies with requirements (passed the tests)	Complies
Requirements (tests) are not applicable to the object under test	Not applicable

TR CU 020/2011 "Electromagnetic compatibility of technical equipment"

Measurement of industrial radio disturbance (IRD). GOST IEC 61000-6-4-2016. Unsymmetrical disturbance voltage (0.15-30 MHz range):

Frequency, MHz	Quasi-peak values		Average values	
	Permissible disturbance level, dB μ V, max.	Disturbance level, dB(uV)	Permissible disturbance level, dB μ V, max.	Disturbance level, dB(uV)
0,15	66,0	44	56,0	37
0,16	65,5	41	55,5	35
0,26	61,1	39	51,1	32
0,38	58,2	35	48,2	30
0,50	56,0	28	46,0	28
1,22	56,0	24	46,0	22
2,54	56,0	21	46,0	19
5,00	56,0	19	46,0	15
7,84	60,0	16	50,0	14
16,33	60,0	14	50,0	12
22,15	60,0	11	50,0	9
30,00	60,0	9	50,0	7

Disturbance power.

Frequency, MHz	Quasi-peak values		Average values	
	Permissible disturbance level, dB(pW), max.	Disturbance level, dB(pW)	Permissible disturbance level, dB(pW), max.	Disturbance level, dB(pW)
30,0	45,0	24,3	35,0	15,0
108,5	47,3	23,5	37,3	14,4
198,5	51,1	22,8	41,1	13,8
300,0	55,0	22,2	45,0	13,2
433,0	55,0	21,7	-	-
515,7	55,0	21,1	-	-
1000,0	55,0	20,6	-	-

GOST 30804.6.2-2013 Immunity to electrostatic discharge

Type of disturbance	Severity level	Voltage, kV	Number of applications	Required performance	Test result
Contact discharge	2	4	10 positive, 10 negative	B	A
Air discharge	3	8	10 positive, 10 negative	B	A

Immunity to high-energy microsecond surge disturbances.

Type of disturbance	Severity level	Pulse voltage amplitude, kV $\pm 10\%$	Required performance	Test result
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Microsecond surges, line-to-line	2	$\pm 1,0$	B	A
Microsecond surges, line-to-earth	3	$\pm 2,0$	B	A

Immunity to electrical fast transient/burst disturbances.

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Type of disturbance	Severity level	Test exposure amplitude, kV	Pulse repetition frequency, kHz	Required performance	Test result
Fast transient/burst disturbances, line-to-line	2	1	5	B	A

Immunity to conducted disturbances induced by radio-frequency fields.

Type of disturbance	Severity level	Exposure frequency range, MHz	Test voltage level, V (dB/uV)	Required performance	Test result
Conducted disturbance induced by radio-frequency emission (via coupling/decoupling networks)	1	From 0.15 to 80	1 (120)	A	A

Immunity to dynamic changes in supply voltage

Type of dynamic change in supply voltage	Electromagnetic environment class	Test exposure			Required performance criterion	Test result
		Test voltage, % of Unom	Amplitude of dynamic voltage change, % of Unom	Duration of dynamic voltage changes, periods		
Voltage dips	2	70	30	50	B	A
Voltage interruptions	2	0	100	1	B	B
Voltage surges	2	120	20	25	B	A

Immunity to radio-frequency electromagnetic field.

Type of disturbance	Severity level	Exposure frequency range, MHz	Test strength, (dB μ V/m) field V/m	Required performance	Test result
Radio-frequency electromagnetic field	2	From 80 to 1000	3(130)	A	A

IMMUNITY. GOST 30804.6.2-2013

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Performance criteria for technical equipment during immunity testing.

Criterion A - during and after the disturbance is applied, the equipment shall continue to operate as intended. No degradation of performance below the level specified by the manufacturer for intended use, and no loss of function, is permitted.

Criterion B - after the disturbance has ceased, the equipment shall continue to operate as intended. No degradation of performance below the level specified by the manufacturer for intended use, and no loss of function, is permitted.

Criterion C - temporary loss of function is permitted provided that the function is self-recovering or can be restored by user operation.

Immunity to electrostatic discharge.

Product test results for compliance with electrostatic-discharge immunity requirements according to GOST 30804.6.2-2013, with test exposures according to GOST 30804.4.2-2013 (direct ESD: contact and air discharge; indirect ESD: contact discharge) are given in Table 4.

Ports tested: enclosure, control buttons, horizontal and vertical coupling planes. Table 4

Type of disturbance	Voltage, kV	Number of applications	Required performance	Result of compliance
Contact discharge	4	10 positive 10 negative	B	Pass
Air discharge	8	10 positive 10 negative	B	Pass

Immunity to electrical fast transient/burst disturbances (EFT/B).

Product test results for compliance with EFT/B immunity requirements according to GOST 30804.6.2-2013, with test exposures according to GOST 30804.4.4-2013, are given in Table 5.

Ports tested: AC mains power port. Table 5

Type of disturbance	Voltage pulse amplitude kV $\pm 10\%$	Required performance	Compliance result
Electrical fast transient/burst (EFT/B)	$\pm 2,0$	B	Pass

Immunity to conducted disturbances induced by radio-frequency fields in the frequency range from 0.15 to 80 MHz.

Product test results for compliance with requirements for immunity to conducted disturbances induced by radio-frequency fields according to GOST 30804.6.2-2013, with test exposures according to STB IEC 61000-4-6-2011, are given in Table 6.

Ports tested: AC mains power port. Table 6

Type of disturbance	Frequency range of exposure, MHz	Test voltage level, V (dB/uV)	Required performance	Compliance result
Conducted disturbances induced by radio-frequency electromagnetic fields. AM 80%, 1 kHz	0,15 - 47, 68 - 80	10(140)	A	Pass
	47 - 68	3(130)	A	Pass

This report applies only to the tested sample

Immunity to radio-frequency electromagnetic field.

Product test results for compliance with radio-frequency electromagnetic-field immunity requirements in the frequency range from 80 to 1000 MHz according to GOST 30804.6.2-2013, with test exposures according to GOST 30804.4.3-2013, are given in Table 7.

Port tested: enclosure port. Table 7

Type of disturbance	Frequency range of exposure, MHz	Test field strength, V/m (dB/uV/m)	Required performance	Compliance result
Radio-frequency electromagnetic field. AM 80%, 1 kHz	80 -1000*	10(140)	A	Pass
	1400 - 2000	3(130)	A	Pass
	2000 - 2700	1(120)	A	Pass

* Excluding broadcasting bands 87-108, 174-230 and 470-790 MHz, where the electric field strength shall be 3 V/m.

Immunity to high-energy microsecond surge disturbances.

Product test results for compliance with high-energy microsecond surge immunity requirements according to GOST 30804.6.2-2013, with test exposures according to STB IEC 61000-4-5-2006, are given in Table 8.

Ports tested: AC mains power port. Table 8

Type of disturbance	Voltage pulse amplitude kV $\pm 10\%$	Required performance	Compliance result
Surge, line-to-line	$\pm 1,0$	B	Pass
Surge, line-to-earth	$\pm 2,0$	B	Pass

Immunity to dynamic changes of supply voltage.

Product test results for compliance with immunity requirements for dynamic supply-voltage variations according to GOST 30804.6.2-2013, with test exposures according to GOST 30804.4.11-2013, are given in Table 9.

Ports tested: AC mains power port. Table 9

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Type of dynamic mains-voltage variation	Test exposure			Required performance criterion	Compliance result
	Test voltage as % of Unom	Amplitude of dynamic voltage variation as % of Unom	Duration of dynamic voltage variations, cycles		
Voltage dips	0	100	1	B	Pass
	40	60	10	Pass	Pass
	70	30	25	Pass	Pass
Interruptions voltage	0	100	250	Pass	Pass

*** Voltage changes at zero crossing.**

Immunity to power-frequency magnetic field.

Product test results for compliance with power-frequency magnetic field immunity requirements according to GOST 30804.6.2-2013, with test exposures according to STB IEC 61000-4-8-2011, are given in Table 10.

Port tested: enclosure port. Table 10

Type of exposure	Test level	Required performance	Result of compliance
Power-frequency magnetic field (PFMF)	30 A/m, 50 Hz	A	Pass

Conclusion:

The samples submitted for testing comply with the requirements of the Technical Regulation of the Customs Union "On safety of low-voltage equipment" (TR CU 004/2011)

Technical Regulation of the Customs Union "Electromagnetic compatibility of technical equipment" (TR CU 020/2011)

This report applies only to the tested sample