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Document Verification Number: 1434-5198-0054-3639(ApPLICANT: SIN BYEONG CHEOL)

Permission Number: 15-961			
Medical Device Manufacturing License			
Business License Number: 3109			
Category	Manufacturing	Item/Item Type	Item
Product Name (Product Name, Item, Model)	Alkaline ionizer, Alkaline ionized water generator, ID-9000 and 1 item	Code Number (Rating)	A86010.01(2)
Shape and Structure	See the attached paper.		
Raw Materials	See the attached paper.		
Manufacturing Method	See the attached paper.		
Purpose in Use	Purpose in Use: See the attached paper. Performance: See the attached paper.		
How to use	See the attached paper.		
Precautions when using	See the attached paper.		
Packing Unit	See the attached paper.		
How to save and Expiration Date	How to save: See the attached paper. Expiration(Validity) Date: See the attached paper.		
Test Specification	Medical Device Screening Number: 1003-20150445-0642 (2015.06.08) Korea Machinery Electric&Electronic Testing Researcher		
Manufacturer(Importer) Information	Manufacturer(Importer) Information: ION CO., LTD 2nd F/L, 15 Oksan-ro 230 Beongil, Wonmi-gu, Bucheon-si, Gyeonggi-do, KOREA Manufacturer: See the attached paper.		
Permission Condition			
Remarks			
<p>I hereby permit as given above pursuant to the article 6 of 「Medical Device Act」 and the clause 2 of the article 5 of the enforcement regulations of the Same Act.</p> <p style="text-align: center;">The 17th Day of June, 2015</p> <p style="text-align: center;">Chief Officer of Gyeongin Regional Korea Food & Drug Administration /Official seal affixed/</p>			

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Test Specification

1. Safety Test

"Common standard specification for electrical and mechanical safety of medical devices"

"Common standard specification for safety of medical equipment electromagnetic waves"

2. Performance Test

No.	Test items	Test Standard	Test Method	Remarks
1	Product material PH test	1. Alkaline water By standard water, the standard PH value in the normal use condition(PH adjustment switch) will be as follows. 1st phase: 8.5 ± 0.5 2nd phase: 9.0 ± 0.5 3rd phase: 9.5 ± 0.3	After setting the mode by pressing the PH control switch on the unit, measure it with the PH meter. (Measured after leaving 500ml.)	
2	Variation test of input power	There should be no obstacle to the appliance when tested according to the test method.	Operate with rated voltage 220V and check if there is any abnormality in the equipment when the rated voltage is changed by $\pm 10\%$.	
3	Processing quantity test	Alkaline water: It should be within 1.6 l/min $\pm 10\%$.	After pressing the extraction button of each mode, measure the discharged water and confirm it.	
4	Safety device	① When alkaline water is selected, it automatically changes the polarity of the electrode and changes the water path(channel switching) each time it stops after four times of operation in order to remove the scale. ② FUSE : If a power supply is short-circuited or if there is a problem with the equipment, a fuse(250V/5A) is installed on the power input side to automatically shut off the equipment. And then the flow of the over-current is blocked.	① Operate the device and check it. ② Check that 250V, 5A Fuse is equipped using the naked eye.	
5	Leak test	There should be no leaks in the filter, electrolytic tank, piping at the water pressure of the front of the main body water supply valve at the minimum water pressure of 0.5kgf/cm ² and maximum 5kgf/cm ² .	Check the water leakage by repeatedly changing the input water pressure.	

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No.	Test Items	Test Standard		Test Method			
6	Product material safety test	A. When tap water or synthesized standard water (excluding spring water and spring water) is used under normal use conditions and the generated alkaline ionized water is checked, it shall conform to all items of water quality standards (tap water standard) excluding pH test.			For the sampling of the "A" test, after passing about 1L, the required amount (about 1L or more) is sampled and confirmed through the test equipment. (※ Only the highest level product of alkaline ionized water should be tested.) ※ In the case of electrolysis method, the total trihalomethane concentration of the raw water ((tap water) should be indicated on the test report.		
		○ Microbiological tests					
		Test Items		Test Standard			
		Common bacteria(Total Colony Counts)		100CFU/ml or less			
		Total Coliform Group(Total Coliforms)		Non-detection/100ml			
		E.coli/Fecal Coliform Group(E.coli/Coliforms)		Non-detection/100ml			
		○ Inorganic/Organic Materials Test					
		Test Items		Test Standard		Test Items	Test Standard
		lead		under 0.01mg/L		carbon tetrachloride	under 0.002mg/L
		arsenic		under 0.01mg/L		tetrachlorethylene	under 0.01mg/L
		selenium		under 0.01mg/L		trichlorethylene	under 0.03mg/L
		cadmium		under 0.005mg/L		1,2-Dibromo-3-chloropropane	under 0.003mg/L
		boron		under 1.0mg/L		trichloroacetoneitrile	under 0.004mg/L
		copper		under 1mg/L		chloral hydrate	under 0.03mg/L
		zinc		under 3mg/L		dibromochloromethane	under 0.1mg/L
		iron		under 0.3mg/L		dichloroacetoneitrile	under 0.09mg/L
		manganese		under 0.05mg/L		Haloacetic acid	under 0.1mg/L
		aluminum		under 0.2mg/L		Formaldehyde	under 0.5mg/L
		mercury		under 0.001mg/L		chloroform	under 0.08mg/L
		fluorine		under 1.5mg/L		total trihalomethane (raw water)	under 0.1mg/L
		nitrate nitrogen		under 10mg/L		total trihalomethane (passing water)	under 0.1mg/L
		chlorine ion		under 250mg/L		1,4-dioxane	under 0.05mg/L
		sulfate ion		under 200mg/L		cabaryl	under 0.07mg/L
		Diazinon		under 0.02mg/L		residual chlorine	under 4.0mg/L
		parathion		under 0.06mg/L		chromium	under 0.05mg/L
		phenitrothion		under 0.04mg/L		ammonia nitrogen	under 0.5mg/L
		dichloromethane		under 0.02mg/L		phenol	under 0.005mg/L
		dichloromethane		under 0.02mg/L		detergent	under 0.5mg/L
		1,1,1-Trichloromethane		under 0.1mg/L		cyan	under 0.01mg/L
		bromodichloromethane		under 0.03mg/L		turbidity	under 0.5NTU
dibromochloromethane		under 0.1mg/L	color	under 5 degree			
benzene		under 0.01mg/L	taste	non-taste			
toluene		under 0.7mg/L	odor	on-odor			
ethylbenzene		under 0.3mg/L	hardness	under 300mg/L			
xylene		under 0.5mg/L	potassium permanganate consumption	under 10mg/L			
1,1-dichloroethylene		under 0.03mg/L	evaporation residue	under 500mg/L			

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No.	Test Items	Test Standard	Test Method
6	Product material safety test	<p>B. Dissolution test: It should be suitable when tested according to the test method.</p> <p>1) PE (Hose)</p> <ul style="list-style-type: none"> - Heavy metals: 1.0mg/l or less (as lead) - KMnO4 consumption: 10mg/l or less - Evaporation residue: 30mg/l or less - 1-Hexene: 3 or less - 1-Octene: 15 or less <p>2) ABS(Electrolytic bath case)</p> <ul style="list-style-type: none"> - Heavy metals: 1.0mg/l or less (as lead) - KMnO4 consumption: 10mg/l or less - Evaporation residue: 30mg/l or less - Acrylonitrile: 0.02 or less <p>3) NBR (O-ring)</p> <ul style="list-style-type: none"> - Heavy metals: 1.0mg/l or less (as lead) - Evaporation residue: 30mg/l or less - Formaldehyde: 4mg/l or less - Phenol: 5mg/l or less - Zinc: 15mg/l or less <p>4) PET(Diaphragm)</p> <ul style="list-style-type: none"> - Heavy metals: 1.0mg/l or less (as lead) - KMnO4 consumption: 10mg/l or less - Evaporation residue: 30mg/l or less - Antimony: 0.04mg/l or less - Germanium: 0.1mg/l or less - Terephthalic acid: 7.5mg/l or less - Isophthalic acid: 5.0mg/l or less <p>5) POM(Solenoid valve, Pump, Flow sensor)</p> <ul style="list-style-type: none"> - Heavy metals: 1.0mg/l or less (as lead) - Evaporation residue: 30mg/l or less - Formaldehyde: 4.0mg/l or less - Potassium permanganate consumption: 10mg/l or less <p>6) Silicon Resin(Packing, Water-piping hose)</p> <ul style="list-style-type: none"> - Heavy metals: 1.0mg/l or less (as lead) - Evaporation residue: 30mg/l or less - Formaldehyde: 4mg/l or less - Phenol: 5mg/l or less - Zinc: 15mg/l or less <p>7) Metal(titanium(platinum coating), SUS(water tank), brass(valve))</p> <ul style="list-style-type: none"> - Arsenic: 0.2mg/l or less - Cadmium: 0.1mg/l or less - Lead: 0.4mg/l or less - Nickel: 0.1mg/l or less - 6 Chrome: 0.1mg/l or less <p>8) PP(Filter Case)</p> <ul style="list-style-type: none"> - Lead: 1.0mg/L or less - Potassium permanganate consumption: 10mg/L or less - Evaporation residue: 30mg/L or less 	<p>Tests shall be performed in accordance with the specifications on drinking water quality standards and inspection, and the test methods for equipment&containers of foodstuff synthetic resin and packaging pursuant to requirements of the Ministry of Environment No. 439.</p>

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7	Performance test of drinking water under the purifying water	All items of material inspection and performance inspection of water purifier standard specification and designated inspection agency should be satisfied.	The performance test of general water purifier shall be carried out according to the standard of water purifier and the material inspection and performance inspection of the designated inspection agency. However, if there is a special function, special water purifier performance test shall be additionally performed.
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31 / 32



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