TEST REPORT NO. _____

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TEST REPORT

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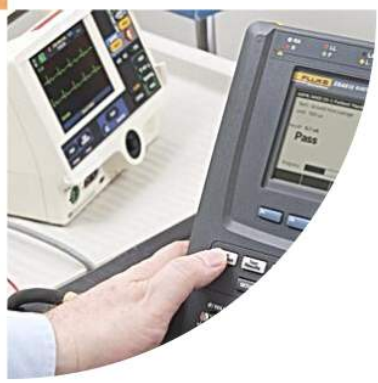

Corporate Office: Office No. 01A, Wing – B,
Siddhesh Optimus, Viman Nagar,
Pune – 411014, Maharashtra, India.

Test House: Sr. No. 82/1, Bajirao Dhawade
Patil Industrial Estate, NDA Road, Shivane,
Pune - 411023, Maharashtra, India

Test Report
ISO 80601-2-74
Medical electrical equipment Part
2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

Report reference No. ..... :	2403009
Approved by (+ signature) ..... :	Kunal Deshpande
Date of issue ..... :	12.04.2024
Testing laboratory ..... :	Astute Labs Pvt. Ltd.
Address ..... :	Office # 01A, B Wing, Siddhesh Optimus, OppLunkad Queensland, S. No. 211, Viman Nagar, Pune – 411014, Maharashtra, India.
Testing location ..... :	Sr. No. 82/1, Bajirao Dhawade Patil Industrial Estate, NDA Road, Shivane, Pune-411023, Maharashtra, India
Applicant ..... :	Heka Medicals India Pvt. Ltd.
Address ..... :	Site I: First Floor, S H Arcade Monippally P O, Kottayam PIN - 686636 Site II: No.354 B-Ground Floor & C- First Floor, Philip Plaza, Elanji Road, Monippally, Monippally P.O, Kottayam PIN-686636
Standard ..... :	Medical electrical equipment Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
Test procedure ..... :	According to ISO 80601-2-74:2021 Medical electrical equipment Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
Procedure deviation ..... :	N/A
Non-standard test method ..... :	N/A
Type of test object ..... :	HekaFlo
Trademark ..... :	HekaFlo
Model/type reference ..... :	HM-P-500
Manufacturer ..... :	Heka Medicals India Pvt. Ltd.
Address ..... :	Site I: First Floor, S H Arcade Monippally P O, Kottayam PIN - 686636 Site II: No.354 B-Ground Floor & C- First Floor, Philip Plaza, Elanji Road, Monippally, Monippally P.O, Kottayam PIN-686636
Rating ..... :	Input: 1) Supplied by AC mains: 100-240VAC, 50/60Hz, 250VA, or 2) Supplied by external adapter: NA or 3) Supplied by internal electric power source: N/A

COPY OF MARKING PLATE

GENERAL INFORMATION	
Test item particulars (see also clause 5):	
Classification of installation and use.....:	~~Transportable~~ / portable / ~~stationary / mobile / fixed / permanently installed / hand-held/ Body-Worn~~
Supply connection .....:	~~Internally powered /permanently installed /~~ Appliance Inlet / ~~non-detachable cord~~
Accessories and detachable parts included in the evaluation :	Auto feed humidification chamber, Heated Breathing circuit, Nasal Cannula, Oxygen Tube, Flow Meter, Air Filter and H-Connector
Options included .....:	Nasal Cannula
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object does meet the requirement .....:	Pass
- test object does not meet the requirement .....:	Fail
- not evaluated.....:	N/E(collateral standards only)
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.	
The sample has been provided by the customer	

General product information and considerations: The HekaFlo is for the treatment of spontaneously breathing patients who will be benefited by supplying high flow warmed and humidified respiratory gases. Based on the patient interface, the flow may be set between 2- 60 L/min. The device can be used in the emergency room, outpatient department, inpatient department and other diagnostic and treatment rooms.

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ISO 80601-2-74			
Clause	Requirement + Test	Result - Remark	Verdict
201.4	**General requirements**		
201.4.3	**ESSENTIAL PERFORMANCE**	RM File Reference to Essential performance: Risk management file HM/RMF/001	Pass
201.4.3.101	**Additional requirements for essential performance** Additional essential performance requirements are found in the subclauses listed in Table 201.101.	Complies	Pass
201.4.6	**ME equipment or ME system parts that contact the patient** aa) The humidifier or its parts or accessories that can come into contact with the patient shall be subject to the requirements for applied parts according to this subclause.	Complies	Pass
201.4.11.101	**Additional requirements for pressurized gas input**		
201.4.11.101.1	**Overpressure requirement** a) If the humidifier is intended to be connected to a medical gas pipeline system conforming with ISO 7396-1:2016+AM D1:2017, then it: 1) shall operate and meet the requirements of this document throughout its rated range of input pressure; 2) shall not cause an unacceptable risk under the single fault condition of 1000 kPa.	Not applicable	N/A
201.4.11.101.2	**Compatibility requirement** If the humidifier is intended to be directly connected to a medical gas pipeline system conforming with ISO 7396-1: 2016+AMD1:2017 then: a) the rated range of input pressure shall cover the range specified in ISO 7396-1:2016+AMD1: 2017; and b) under normal condition, 1) the maximum 10 s average input flowrate required by the humidifier for each gas shall not exceed 60 l/min at a pressure of 280 kPa, measured at the gas intake port, and 2) the transient input flowrate shall n o t exceed 200 l/min averaged for 3 s. or: 3) the accompanying documents shall disclose: i) the maximum 10 s average input flowrate required by the humidifier for each gas at a pressure of 280 kPa, measured at the gas intake port; ii) the maximum transient input flowrate averaged for 3 s required by the humidifier for each gas at a	Not applicable	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	pressure of 280 kPa, measured at the gas intake port; iii) a warning to the effect that this humidifier is a high-flow device and should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high-flow at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flow, thereby minimizing the risk that the humidifier interferes with the operation of adjacent equipment.		
201.4.101	**Additional general requirements** Humidifiers are frequently used in combination with other respiratory ME equipment or medical devices. The basic safety and essential performance of both the humidifier and the other respiratory ME equipment or medical device are interdependent. a) Where a humidifier is intended to be used in combination with other respiratory ME equipment or medical devices as indicated in its instructions for use, it shall be evaluated in combination with the other respiratory ME equipment or medical devices when applying the requirements of this document. b) As appropriate, the requirements of the particular standards of the other respiratory ME equipment or medical devices indicated in the instructions for use of the humidifier shall also apply to the combination of the humidifier and other respiratory ME equipment or medical devices.	Complies	Pass
201.5	**General requirements for testing of ME equipment**		
201.5.4	**Other condition** aa) Unless otherwise specified, the liquid container and liquid reservoir, if provided, shall be filled to maximum capacity, as indicated in the instructions for use, at the beginning of a test with distilled water at the ambient test temperature. bb) For the purpose of checking conformance with requirements of this document, the delivered gas temperature shall be sensed in the breathing tube not more than 50 mm from the patient-connection port (see Annex BB).	The instruction for use recommends sterile water for filling in the humidification chamber up to the maximum level mark on the chamber. HM/UM/002	Pass
201.5.101	**Additional requirements for general requirements for testing of ME equipment**		
201.5.101.1	**Humidifier test conditions** a) Where a humidifier is intended to receive a medical gas supply as specified for normal use: 1) oil-free industrial grade oxygen or air may be substituted for the equivalent medical gas; and 2) the moisture content shall be less than 1 mg/l	Complies	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Where a humidifier is intended to receive room air in normal use, such as in combination with a blower device, 1) the incoming air shall be at a low moisture content within the labelled range of humidity of normal use appropriate to the incoming air temperature. 2) drier air is preferred a sit provides more margin below dew point in which to demonstrate humidification output.		
201.5.101.2	**Gas flowrate and leakage specifications** In this document, requirements for the flowrate, volume and leakage a) are expressed at standard temperature and pressure, dry (STPD), b) except for those associated with the breathing system, which are expressed at body temperature and pressure, saturated (BTPS).	BTPS Complies	Pass
201.5.101.3	**Humidifier testing errors** a) For the purposes of this document, acceptance criteria for testing declared tolerances shall use the type A evaluation method (statistical uncertainty) procedure from IEC Guide 115, 4.4.2. b) Test equipment and methods shall be selected and controlled to ensure that the uncertainty (with coverage factor k = 2, for confidence of- 95 %) is no more than 30 % of the disclosed tolerance for the parameter being tested. c) For the purposes of this document, declared tolerances shall be adjusted by the measurement uncertainty. d) The manufacturer shall disclose the measurement uncertainty of each disclosed tolerance in the technical description.	Complies	Pass
201.6	**Classification of ME equipment and ME systems**		
201.6.101	**Humidifier classification**		
201.6.101.1	**Category 1** A humidifier intended for use in patients whose upper airways have been bypassed (invasive therapy) shall be classified as category 1.	Not applicable	N/A
201.6.101.2	**Category 2** A humidifier intended for use in patients whose upper airways have not been bypassed (i.e. intended for non-invasive ventilation, sleep apnoea CPAP therapy) shall be classified as category 2 unless it is intended for use in high-flow therapy.	Not applicable	N/A
201.6.101.3	**Category 3** A humidifier intended for use with non-sealed airway devices in high-flow therapy (i.e., constant	Complies	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	delivered flow that is intended to exceed the inspiratory flow of the patient), in patients whose upper airways have not been bypassed, shall be classified as category 3.		
201.6.101.4	**Classification** a) A humidifier, in each mode of operation, shall be classified either as: 1) category 1; 2) category 2; or 3) category 3. b) A humidifier may be classified a s different categories over specified ranges of flowrates and temperatures as well as intended use.	Category 3	Pass
201.7	**ME equipment identification, marking and documents**		
201.7.1.101	**Information to be supplied by the manufacturer** a) The information supplied by the manufacturer of a humidifier and its accessories shall conform with ISO 20417:2021. b) In applying ISO 20417:2021, the terms in this document and those in IEC 60601-1:2005+A1:2012+A2: 2020 shall be used as follows. 1) The term "accompanying information" shall assume the same meaning as accompanying documents. 2) T h e term "medical device" shall assume the same meaning a s ME equipment. 3) The term "user" shall assume the same meaning as operator. 4) The term "patient" shall include animals.	Complies	Pass
201.7.2.4.101	**Additional requirements for accessories** Accessories supplied separately shall fulfil the requirements of: a) 201.7.2.101; and b) be marked with an indication of any limitations or adverse effects of the accessory on the basic safety or essential performance of the humidifier, if applicable. 1) If marking the accessory is not practicable, this information may be placed in the instructions for use.	Complies	Pass
201.7.2.5	**ME equipment intended to receive power from other equipment**	Equipment is not intended to get power from other equipment	N/A
201.7.2.8.2	**Other power sources**	Not applicable	N/A
201.7.2.101	**Additional requirements for marking on the outside of ME equipment or ME equipment parts** a) The marking of ME equipment, its parts or accessories shall:	Complies	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	1) be clearly legible; and 2) include the following, if necessary to maintain basic safety or essential performance of the humidifier: i) the minimum liquid level; ii) the maximum liquid level. b) If applicable, marking of operator-accessible ME equipment, its parts or accessories shall include the following: 1) an arrow indicating the direction of the flow for flow-direction-sensitive components that are operator-removable without the use of a tool; 2) if a pressure-relief protection device i s provided, the pressure a t which i t opens; i) This marking shall be on or near the pressure-relief protection device. c) For a 'humidifier intended to be used in the magnetic resonance (MR) environment, the humidifier, its parts and accessories shall have clearly legible markings conforming with: 1) symbol 7.3.1-1 of IEC 62570 (Table 201.0.2.101, symbol 2) if 'MR Safe'; 2) symbol 7.3.1-2 of IEC 62570 (Table 201.0.2.101, symbol 3) if 'MR Safe'; or 3) symbol 7.3.2 of IEC 62570 (Table 201.0.2.101, symbol 4) if 'MR Conditional',		
201.7.4.3	**Units of measurement** All gas volume, flowrate and leakage specifications: aa) shall be expressed at STPD; except bb) for those associated with the breathing system which shall be expressed at BTPS	Complies	Pass
201.7.9.2.1	**General**		
201.7.9.2.1.101	**Additional general requirements** a) For a humidifier intended for use in the home healthcare environment, separate instructions for use shall be provided for: 1) the lay operator; 2) the supervising clinician or the healthcare professional operator. b) The manufacturer may choose in which instructions for use to place the information required by this document unless otherwise indicated in this document based on risk management and usability considerations. c) The supervising clinician or the healthcare professional operator instructions for use shall include the information contained in the lay operator instructions for use.	Complies	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
201.7.9.2.1.102	**Additional general requirements** The instructions for use shall include a statement: a) on the quality and purity of the water to be used in the humidifier, and b) that adding other substances can have adverse effects.	User manual recommends the usage of sterile water	Pass
201.7.9.2.2.101	**Additional requirements for warnings and safety notices** The instructions for use shall include: a) a warning statement to the effect that "WARNING: Do not add any attachments or accessories to the humidifier that contravene the instructions for use of the humidifier or accessory as the humidifier might not function correctly affecting the quality of the therapy or injuring the patient." b) a warning statement to the effect that "WARNING: Do not use the humidifier at an altitude above [insert maximum rated altitude] or outside a temperature of [insert rated temperature range]. Using the humidifier outside of this temperature range or above this altitude can affect the quality of the therapy or injure the patient." c) a warning statement to the effect that "WARNING: To prevent disconnection of the tubing or tubing system during use, especially during ambulatory use, only tubes in conformance with ISO 5367 or ISO 80601-2 -74 should be used". d) if applicable, a warning statement to the effect that "WARNING: Covering breathing tubes with a blanket or heating them in an incubator or with an overhead heater can affect the quality of the therapy or injure the patient." e) if applicable, a warning statement to the effect that "WARNING: The humidifier shall not be used with nitric oxide. Such use might cause the humidifier to not function correctly causing serious deterioration of health." f) a warning statement to the effect that "WARNING: Use of the humidifier with a gas source (e.g. a blower/turbine-based ventilator) that heats the gas provided to the humidifier above a temperature of [insert rated temperature limit] can result in impaired humidification output with the potential to cause severe deterioration of health."	Complies	Pass
201.7.9.2.6	**Installation** The instructions for use shall give recommended mounting methods and other relevant information for installation of the humidifier.	Refer user manual HM/UM/002 Rev. No. 00	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
201.7.9.2.8.101	**Additional requirements for start-up procedure** a) If the humidifier is equipped with an alarm system, then the instructions for use for the lay operator shall disclose a method by which the alarm signals can be functionally tested to determine if they are operating correctly. b) Portions of this test method may: 1) be performed automatically by the humidifier; or 2) require operator action. c) The specifications of any required accessories or test equipment needed to perform these tests shall be disclosed in the instructions for use.	Complies	Pass
201.7.9.2.9.101	**Additional requirements for operating instructions**		
201.7.9.2.9.101.1	**Lay operator operating instructions** The instructions for use for the lay operator shall include: a) the conditions under which the humidifier maintains the accuracy of controlled and displayed variables as disclosed in the instructions for use; b) an explanation of the meaning of the IP classification marked on the ME equipment; c) the maximum volume of water, expressed in ml, available for vaporization contained in the liquid container and, if provided, in the liquid reservoir; d) an indication of the expected duration of operation between refills, under specified operating conditions;	Device is intended to be used in healthcare environment with the supervision of trained staffs	N/A
201.7.9.2.9.101.2	**Supervising clinician operating instructions** The instructions for use intended for the supervising clinician or the healthcare professional operator shall include: a) the maximum limited pressure of: 1) the humidifier, and 2) the accessories; b) the maximum operating pressure; c) the minimum operating pressure of the humification chamber, if applicable; d) the rated range of environmental operating conditions (temperature and altitude) of normal use; e) the maximum delivered gas temperature, if the humidifier is not provided with a means of continuously indicating the measured gas temperature;	Complies	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	f) the location in the humidifier or accessories to which the displayed measured gas temperature is referenced; g) the gas leakage of the humidifier or individual components, as appropriate, at the maximum rated pressure. The gas leakage should be determined in accordance with ISO 5367 or an equivalent method. The gas leakage for an active HME should be determined in accordance with ISO 9360-1 or ISO 9360-2[41]; h) unless the humidifier is integrated into other equipment, 1) The rated range of the following characteristics of the assembled operator- detachable parts, over which the accuracies of set and monitored humidification are maintained: i) flowrate; ii) gas pathway resistance; and iii) gas pathway compliance. 2) These specifications may be presented in ranges. 3) The accuracies of set and monitored values may be presented as a function of these characteristics. 4) Since these values can be affected by the depletion of the liquid, the minimum and maximum values shall be disclosed. 5) Compliance and resistance can be nonlinear. These characteristics might need to be specified over a range (e.g. at 1 5 1/min, 3 0 1/min, 60 1/min, maximum flowrate and the maximum rated pressure). 6) The resistance and compliance should be determined in accordance with ISO 5 3 6 7 or an equivalent method. 7) The resistance and compliance for an active HME should be determined in accordance with ISO 9360-1 or ISO 9360-2 [41]. i) unless the humidifier is integrated into other equipment, the pressure drop, as a function of flowrate, across the humidifier and accessories or individual components; 1) The pressure drop should be determined in accordance with ISO 5367 or an equivalent method. 2) The pressure drop for an active HME should be determined in accordance with ISO 9 3 60 - 1 or ISO 9360-2[41]		

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Clause	Requirement + Test	Result - Remark	Verdict
	j) unless the humidifier is integrated into other equipment, the rated range of gas inlet temperature; k) unless the humidifier is integrated into other equipment that provides control of gas flow and pressure to the patient, any restrictions on the ventilation modes, pressures or flow patterns applied to the humidifier and its accessories from equipment indicated in the instructions for use; and l) the known adverse effects on the performance of the humidifier when exposed to, for example, electrocautery, electrosurgery, defibrillation, X-ray (gamma radiation), infrared radiation, conducted transient magnetic fields including magnetic resonance imaging (MRI), and radiofrequency interference. If applicable, instructions for use shall disclose m) the essential technical characteristics of each recommended breathing system filter; n) for a humidifier that entrains air for the purpose of diluting oxygen: 1) a statement to the effect that the oxygen concentration can be affected by a partial obstruction downstream of the humidifier, e.g. when using accessory equipment; 2) a recommendation that the oxygen concentration be measured a t the point of delivery to the patient		
201.7.9.2.12	**Cleaning, disinfection and sterilization** or in single fault condition aa) The instructions for use shall identify the portions of the gas pathways through the humidifier that can become contaminated with body fluids or by contaminates carried by expired breathing gases during both normal condition and single fault condition.	Complies	Pass
201.7.9.2.13.101	**Additional requirements for maintenance** The instructions for use shall disclose a) a description of periodic visual safety inspections that should be performed by the operator, b) the intervals at which cleaning procedures need to be performed and the items required for such cleaning; and c) if applicable, the internal electrical power source care and maintenance procedures, including instructions for recharging or replacement.	Complies	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
201.7.9.2.14.101	**Additional requirements for accessories, supplementary equipment, used Material** The instructions for use of a humidifier shall identify: a) at least one set of accessories; and b) if applicable, the ME equipment necessary for the humidifier's intended use. c) any restrictions on the positioning of components within the breathing system; and d) any adverse effect of any recommended accessory on the essential performance or basic safety of the humidifier or equipment to which it is connected.	Complies	Pass
201.7.9.3.1.101	**Additional general requirements** The technical description shall disclose a) the interdependence of control functions, and b) a statement to the effect that the responsible organization should ensure the compatibility of the humidifier and all of the parts and accessories used to connect to the patient or other equipment before use.	Complies	Pass
201.7.9.3.101	**Additional requirements for the technical description** The technical description shall disclose: a) a description of a method for checking the function of the alarm system for each of the alarm conditions specified in this document, if not performed automatically during start-up; and b) which checks are performed automatically.	Complies	Pass
201.8	**Protection against electrical hazards form ME equipment**		
201.8.3.101	**Additional requirements for classification of applied parts** The applied parts of a humidifier and its accessories shall be F-type applied parts.	Type BF applied part	Pass
201.8.7.4.7	**Measurement of the patient leakage current** Assemble the humidifier to the breathing tube and other necessary accessories. Wrap the metal foil around outside of the patient-connection port, as well as inside to depth that accessible by the relevant standard test finger, as mentioned under 8. 7.4.6. The metal foil is considered as the only patient connection for the applied part concerned	Complies	Pass
201.9	**Protection against mechanical hazards of ME equipment and ME systems**		
201.9.4.3.101	**Additional requirements for instability from unwanted lateral movement** a) A transit-operable humidifier intended for use in either the home healthcare environment or	Complies	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	emergency medical services environment shall include a means by which the humidifier can be easily attached without the use of a tool to prevent unwanted movement during transport while in use. 1) The means shall hold the humidifier to withstand accelerations or decelerations of 1,0 g longitudinal (forward, backward) and 1,0 g transverse (left, right) for at least 3 s each. 2) No more liquid than i s specified in 201.13.1.101 shall exit the humidification chamber outlet from these accelerations or decelerations.		
201.9.6.2.1.101	**Additional requirements for audible acoustic energy** The A-weighted sound pressure level emitted by the humidifier, not integrated into ME equipment that is covered by another particular standard, shall be less than 50 dB as determined by the test method of this document.	Complies	Pass
201.9.6.2.1.102	**Additional requirements for audible acoustic energy for use with an incubator** A humidifier with the breathing tube and other necessary accessories intended for use with an incubator shall conform with the sound pressure level requirements of IEC 60601-2-19:2020, 20 1.9.6.2.1.101.	Not applicable	N/A
201.10	**Protection against unwanted and excessive radiation hazards**	Not applicable	N/A
201.11	**Protection against excessive temperatures and other hazards**		
201.11.1.1	**Maximum temperature during normal use** aa) The heating element of a humidifier shall provide means to ensure that it is unlikely to be touched while exceeding the temperature limits indicated in IEC 60601-1:2005+AM01:2012+AM02:2020, Table 23. 1) Safety sign 7010-W017 (Table 20 1.0.2.102, safety sign 1) may be used to fulfil this requirement. 2) Symbol 60417-5041 (Table 201.0.2.101, symbol 1) in combination with a warning indicator light (see IEC 60601-1:2005+AM01:2012+AM02 :2020, Table 2) may be used to fulfil this Requirement.	Complies	Pass
201.11.1.2.2	**Applied parts not intended to supply heat to a patient** Notwithstanding the requirements of IEC 60601-1:2005+AM01:2012, 11.1.2.2, the allowable maximum temperature of the accessible part	Complies	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	surfaces of breathing tubes within 25 Cm of the patient-connection port shall not reach the following limits:		
	aa) during thermal stability: 44 °C; and	Complies	Pass
	bb) during a change in average flow or other disturbance: 48 °C for not more than 10 min.	Complies	Pass
201.11.6.2	**Overflow in ME equipment** a) Liquid overflowing from the liquid container or liquid reservoir shall 1) not wet any means of protection that is liable to be adversely affected by liquid, nor 2) result in the loss of basic safety or essential performance. b) No hazardous situation (as specified in IEC 60601-1:2005+AMD1:2012 +AMD2:2020,13.1 or 201.13.1.101) or unacceptable risk due to overflow shall be developed: 1) if the liquid container or liquid reservoir is filled to its maximum capacity; 2) for a portable humidifier (e.g. tabletop), if it is tilted through an angle of 10° from any position of normal use when operated under normal condition at the maximum flowrate of normal use; 3) for a mobile humidifier (e.g. pole-mounted), if it is i) tilted through an angle of zoo from any position of normal use, and ii) moved over a threshold as described in IEC 60601-1 :2005+AMD1:2012,9.4.2.4.3, and 4) for an active HME, in the least favourable orientation; when operated under normal condition at the maximum flowrate of normal use.	Complies	Pass
201.11.6.6	**Cleaning and disinfection of ME equipment or ME system** aa) Gas pathways through the humidifier and its accessories not intended for single use that can become contaminated with body fluids or by contaminants carried by expired gases during normal condition or single fault condition that are not single use shall be designed to allow for: 1) cleaning and disinfection; or 2) cleaning and sterilization. 3) Dismantling may be used.	Not applicable	N/A
	bb) Humidifier enclosures shall be designed to allow for surface cleaning and disinfection to reduce to acceptable levels the risk of cross infection of the operator, other persons or next patient.	Complies	Pass
	cc) Processing instructions for the humidifier and its accessories shall	Not applicable	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	1) conform to ISO 1 7664:2017 and ISO 14937:2009, and 2) be disclosed in the instructions for use		
201.11.6.7	**Sterilization of ME equipment or ME system**	No sterilization requirement.	N/A
201.11.7	**Biocompatibility of ME equipment and ME systems** aa) T h e manufacturer o f a humidifier, breathing system, its parts and accessories shall address in the risk management process the risks associated with the leaching or leaking of substances into the gas pathway.		N/E
	bb) The gas pathways shall be evaluated for biocompatibility according to ISO 18562-1:2017.		-
201.12	**Accuracy of controls and instruments and protection against hazardous outputs**		
201.12.1	**Accuracy of controls and instruments** aa) T h e humidifier may provide means to reduce the visibility of its controls and indicators either automatically or by the operator action. bb) If provided, the humidifier shall automatically resume normal visibility during an alarm condition. cc) The controls and indicators related to the essential performance of a humidifier shall be clearly legible under the conditions specified in 7.1.2 of IEC 60601- 1:2005+AMD1:2012+ AMD2:2020, but: 1) for a transit-operable humidifier with the light level extended from the range of ' 100 lx to 1500 lx' to the range of '100 lx to 10000 lx'; and 2) if the intended use of the humidifier includes treatment of highly infectious patients, with the intended position of the operator for the purpose evaluating the legibility of markings shall be at least 2 m from the humidifier.	Complies	Pass
201.12.1.101	**Humidification output** a) Over the range of flowrates, settings, ambient temperature, and gas inlet temperature and humidity of normal use, the humidification output at the patient-connection port shall not be less than: 1) 33 mg/1 for a humidifier operating in a category 1 mode; 2) 10 mg/l for a humidifier operating in a category 2 mode; and 3) 16 mg/l for a humidifier operating in a category 3 mode. b) The humidification output shall either be:	Complies	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	1) determined for each breathing system configuration indicated in the instructions for use; or 2) determined for the worst-case breathing system configurations indicated in the instructions for use. c) If worst-case breathing system configurations are used, the rationale for their selection shall be documented in the risk management file. d) The humidification output (in mg/l) over the rated range of gas flowrates and settings shall be disclosed in the instructions for use.		
201.12.1.102	**Measured gas temperature alarm condition** a) A category 1 or a category 3 humidifier shall be equipped with an alarm system that includes an alarm condition to indicate that the measured gas temperature when averaged over a 5 min period, differs by more than ±2 °c from the set temperature during normal use. b) This alarm conditions shall be at least a medium priority alarm condition, unless 1) an intelligent alarm system, based on additional information, determines that the measured gas temperature alarm condition: i) is suppressed, or ii) its priority is changed. c) This alarm condition need not be activated during the start-up period or during the transition to a new state of thermal equilibrium following a change in gas average flowrate or change in set temperature. d) The maximum start-up period in normal use, the warm-up time for the measured gas temperature to reach the set temperature from a starting temperature of (23 ± 2) °c, shall be disclosed in the instructions for use.	Complies	Pass
201.12.1.103	**Measured gas temperature monitoring equipment** a) The humidifier may be equipped with measured gas temperature monitoring equipment that displays the temperature. b) If equipped, the measured gas temperature monitoring equipment shall 1) have a rated range of at least 25 °c to 45 °C, and 2) be accurate to ±2 ° cover the rated range. c) The accuracy of the measured gas temperature monitoring equipment shall be disclosed in the instructions for use.	Complies	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
201.12.1.104	**Static temperature stability** a) The stability of the temperature at the patient-connection port of a humidifier when operating in normal condition shall be disclosed in the instructions for use. b) The stability of the performance of a humidifier shall either be: 1) determined for each breathing gas pathway configuration indicated in the instructions for use; or 2) for the worst-case breathing gas pathway configuration indicated in the instructions for use. c) If worst case breathing gas pathway configurations are used, the rationale for their selection shall be documented in the risk management file.	Complies	Pass
201.12.1.105	**Dynamic temperature stability** a) For a category 1 humidifier, with the humidifier operating in normal condition, the stability of the dynamic measured gas temperature accuracy shall be disclosed in the instructions for use, as the mean and standard deviation between the set temperature and the measured gas temperature. b) The accuracy of the performance of the humidifier shall either be: 1) determined for each breathing gas pathway configuration indicated in the instructions for use; or 2) for the worst-case breathing gas pathway configuration indicated in the instructions for use. c) If worst-case breathing gas pathway configurations are used, the rationale for their selection shall be documented in the risk management file. d) The accuracy of the performance of the humidifier may be disclosed separately for the following ranges of intended tidal volume: 1) $V_{tidal} \geq 300$ ml; 2) 300 ml $\geq V_{tidal} \geq 50$ ml; and 3) $V_{tidal} \leq 50$ ml.	Not applicable	N/A
201.12.4	**Protection against hazardous output**		
201.12.4.101	**Thermal overshoot** In normal use and single fault conditions and over the rated flowrate range and at the maximum rated operating temperature, the delivered gas temperature of the humidifier, when averaged over 120 s, shall not exceed: 1) 70 °c; and	Complies	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	2) an energy equivalent to 43 °c and 100 % relative humidity (a specific enthalpy not to exceed 197 kJ/m³ dry air). Table 201.104 contains examples of combinations of temperature and relative humidity for air with such a specific enthalpy.		
201.12.4.102	**Low humidification output alarm condition** a) A category 1 or a category 3 humidifier shall be equipped with an alarm system that detects a technical alarm condition indicating the presence of a fault condition that can cause the humidification output at the patient-connection port to be lower than the values listed in 201.12.1.101. b) This alarm condition shall be at least medium priority, unless 1) an intelligent alarm system, based on additional information, determines that the minimum humidification output alarm condition: i) is suppressed; or ii) its priority is changed. c) This alarm condition need not be activated during the start-up period or during the transition to a new state of thermal equilibrium following a change in gas average flowrate or change in set temperature.	Complies	Pass
201.13	**Hazardous situations and fault conditions for ME Equipment**		
201.13.1.101	**Additional specific hazardous situations** In normal condition and single fault condition, a humidifier shall be so constructed that the following hazardous situations shall not occur: a) the volume of liquid exiting the humidification chamber outlet shall not exceed: 1) 1,0 ml in 1 min or 2,0 ml in 1 h when intended for use with patients weighing less than 5 kg; 2) 5 ml in 1 min or 20 ml in 1 h for all other patients.	Complies	Pass
201.13.2.101	**Additional specific single fault conditions** A humidifier shall be so constructed that the following single fault conditions shall not cause an unacceptable risk: a) operation of the humidifier without any liquid; b) if the humidifier includes a sensor or sensors that are responsible for the condition of the gas delivered to the patient, any failure of a sensor or the sensing system. c) operation of the humidifier outside of the rated flowrate.	Complies	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
201.13.102	**Independence of humidification output control function and related risk control measures** a) A single fault condition shall not cause the simultaneous failure of: 1) the humidifier-control function; and 2) the appropriate protection device. b) A single fault condition shall not cause either: 1) the humidifier-control function and the corresponding monitoring equipment or 2) the humidifier-control function and the corresponding alarm system to fail in such a way that the loss of the humidifier-control function is not detected.	Complies	Pass
201.14	**Programmable electrical medical systems (PEMS)**		
201.14.1	**General**		
	aa) The humidity and temperature control PESS of the humidifier PEMS, unless there is an independent risk control measure implemented external to the PESS, shall be considered as 1) for a category 1 or category 3 humidifier, software safety Class C as specified in IEC 62304:2006+AMD1:2015.	Complies	Pass
	2) for a category 2 humidifier, at least software safety Class 8 as specified in IEC 62304:2006+AMD1:2015.	Not applicable	N/A
	bb) The software safety class for a category 2 humidifier shall not be reduced from Class 8 to Class A with an independent hardware risk control measure.		
201.15	**Construction of ME equipment**		
201.15.101	**Mode of operation** A humidifier shall be suitable for continuous operation.	Classified as Continuous operation	Pass
201.16	**ME systems**		
201.16.1.101	**Additional general requirements for ME systems** Accessories connected to the humidifier shall be considered to: a) be part of the humidifier; or b) form an ME system with the humidifier.	Not applicable	N/A
201.16.2	**Accompanying documents of an ME system** - if applicable, a description of the use scenarios and ranges of temperature and flowrate from a ventilator at the gas inlet port of the humidifier which can lead to the failure of a humidifier to function according to its specification.	Not applicable	N/A
201.17	**Electromagnetic compatibility of ME equipment and ME systems**	Tested separately	-
201.101	**Breathing system connectors and ports**		
201.101.1	**General**		

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Clause	Requirement + Test	Result - Remark	Verdict
	a) If a humidifier is intended to be placed in a breathing system, any conical connector shall 1) conform with ISO 5356-1:2015, or 2) not engage with those connectors or with connectors conforming with ISO 80369-1:2018. b) A non-conical connector shall 1) not engage with a conical connector conforming with ISO 5356-1:2015, unless they conform with the engagement, disengagement and leakage requirements of that standard.	Not applicable	N/A
201.101.2	**Patient-connection port** If equipped, the patient-connection port shall be one of the following: a) a female 15 mm conical connector conforming with ISO 5356-1: 2015;	Complies	Pass
	b) a coaxial 15 mm/ 22 mm conical connector conforming with ISO 5356-1: 2015; or	Complies	Pass
	c) for a breathing system intended to only connect to a non-sealed airway device, 1) a female 22 mm conical connector conforming with ISO 5356-1 :2015, or	Complies	Pass
	2) a connector that does not engage with a conical connector conforming with ISO 5356-1 :2015 unless it conforms with the engagement, disengagement and leakage requirements of that standard.	Complies	Pass
201.101.3	**Flow-direction-sensitive components** If the humidifier incorporates any flow-direction-sensitive components, the humidifier shall be so designed that incorrect connection does not present an unacceptable risk to the patient.	Not applicable	N/A
201.101.4	**Accessory port** If provided, each accessory port of the humidifier, breathing system, its parts and accessories shall a) conform with ISO 80369-1 : 2018; b) be provided with a means to secure the accessory in position; and c) be provided with a means to secure closure after removal of the accessory.	Complies	Pass
201.101.5	**Monitoring probe port** If a port is provided for introduction of a monitoring probe, it: a) shall not be compatible with connectors specified in ISO 5356-1: 2015 ; b) shall be provided with a means to secure the probe in position; and c) shall be provided with a means to secure closure after removal of the probe	Not applicable	N/A
201.101.6	**Oxygen inlet port**	Not applicable	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	a) An oxygen inlet connector of the humidifier, breathing system, its parts and accessories that is operator-accessible without the use of a tool shall conform with ISO 80369-1 :2018. b) A humidifier with this inlet connector shall maintain basic safety and essential performance with oxygen supply systems up to 150 hPa, in normal condition.		
201.101.7	**Gas input and gas output ports** **The gas input and output ports of the humidifier shall be one of the following** a) a male 22 mm conical connector conforming with ISO 5356-1: 2015.	Not applicable	N/A
	b) a male 15 mm conical connector conforming with ISO 5356-1: 2015.	Not applicable	N/A
	c) a coaxial 1 5 mm/ 2 2 mm conical connector conforming with ISO 5356-1:2015.	Not applicable	N/A
	d) a non-conical connector that does not engage with a conical connector conforming with ISO 5356-1: 2015.	Not applicable	N/A
	e) a male 1 1, 5 mm conical connector conforming with ISO 5356-1:2015., if the humidifier is only intended for tidal volumes of less than 300 ml.	Not applicable	N/A
201.101.8	**Removable temperature sensors and ports**	Not applicable	N/A
201.101.8.1	**Security** When the sensors or mating ports are engaged in normal use, the connection shall not become disconnected under the conditions of a) no flow, or b) maximum rated flowrate.	Not applicable	N/A
201.101.8.2	**Leakage** The leakage from an engaged sensor or mating port shall not exceed 5 ml/ min at a pressure of 60 cmH2O.	Complies	Pass
201.101.8.3	**Construction** Removable sensors and ports shall a) meet the dimensional requirements of Annex EE, or b) be sufficiently different that they cannot be interchanged with those that do.	Complies	Pass
201.101.9	**Other orifices** If the humidifier, breathing system, its parts and accessories incorporate an independent filling or accessory orifice (e.g. an air entrainment or a heater orifice), that orifice shall not accept any of a) the connectors specified in ISO 5356-1: 2015., or b) the connectors conforming with ISO 80369-1 : 2018.	Complies	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
201.102	**Requirements for the breathing system and accessories**		
201.102.1	**General**		
	The parts and accessories that can affect the basic safety or essential performance of a humidifier shall conform with the requirements of this document, whether they are produced by the manufacturer of the humidifier or by another entity ("third-party manufacturer") .	Complies	Pass
201.102.2	**Labelling** a) The model or type reference of at least one compatible humidifier shall be disclosed in the accompanying document, or packaging label provided with each breathing system or accessory, conforming with 201.102.1. b) Statements shall be included in the accompanying document or packaging label of each breathing system, part or accessory to the effect that: 1) breathing systems, their parts and accessories are validated for use with specific humidifiers; 2) incompatible parts can result in degraded performance which can affect safety; 3) the responsible organization i s accountable for the compatibility of the humidifier and all of the parts and accessories used to connect to the patient and other equipment before use.	Complies	Pass
201.102.3	**Breathing tubes**		
201.102.3.1	**Non-heated breathing tubes** Breathing tubes, other than heated breathing tubes, intended for use in the breathing system shall conform with ISO 5367: 2014 at the maximum humidification output of the humidifier.	Not applicable	N/A
201.102.3.2	**Heated breathing tubes** Heated breathing tubes intended for use in the breathing system shall not collapse on bending, occlude or otherwise cause loss of basic safety or essential performance when the breathing tubes are subject to the maximum rated output power of the specified heated breathing tube controller, including under conditions of no flow.	Complies	Pass
201.103	**Liquid container**		
201.103.1	**Liquid level** Means shall be provided to permit the operator to determine the liquid level without dismantling the humidifier: a) in the liquid container; b) if provided, the liquid reservoir;	Complies	Pass
201.103.2	**Filling cap**	Complies	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	Reusable filling caps, if provided, shall be tethered to part of the humidifier.		
201.104	**Functional connection**		
201.104.1	**General**		
	Basic safety and essential performance of the humidifier shall be maintained if a) connections to the functional connection of a humidifier, including the heated breathing tube controller, are disrupted, b) when any wire in the functional connection is opened or shorted to any other wire in the functional connection, or c) the equipment connected to those parts fails.	Complies	Pass
201.104.2	**Connection to an electronic health record** A category 1 or category 3 humidifier should be equipped with a functional connection that permits data transmission from the humidifier to, for example, an electronic health record.	Not applicable	N/A
201.104.3	**Connection to a distributed alarm system** A category 1 or category 3 humidifier should be equipped with a functional connection that permits connection to a distributed alarm system.	Complies	Pass
201.104.4	**Connection for remote control** A humidifier may be equipped with afunctional connection for external control of the humidifier.	Not applicable	N/A
202	**Electromagnetic disturbances - Requirements and tests**	Complies	Pass
202.4.3.1	**Configurations** aa) attachment of the breathing tubes to the humidifier or heated breathing tube controller;	Complies	Pass
	bb) if applicable, attachment of accessories as necessary to achieve the basic safety and essential performance of the humidifier.	Complies	Pass
202.5.2.2.1	**Requirements applicable to all ME equipment and ME systems**	Complies	Pass
202.8.1.101	**Additional general requirements** a) The following degradations, if affecting basic safety, shall not be allowed: 1) component failures; 2) changes in programmable parameters or settings; 3) reset to default settings; 4) change of operating mode; and 5) the specific enthalpy at the patient-connection port averaged over 120 s exceeding 197 kJ/m3. i) The control signal to the heater may be monitored to determine if heating is unaffected in lieu of monitoring specific enthalpy.	Complies	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	ii) The duration of monitoring of the control signal shall be determined by the manufacturer based on the time constant of the heater control system. b) The humidifier may exhibit temporary degradation of performance (e.g. deviation from the performance indicated in the instructions for use during immunity testing) that does not affect basic safety or essential performance. 1) The control signal to the heater may be monitored to determine if heating is unaffected in lieu of monitoring humidification output. 2) The duration of monitoring of the control signal shall be determined by the manufacturer based on the time constant of the heater control system.		
206	**Usability**		
208	**General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems**		
208.6.8.4. 101	**Additional requirements for termination of alarm signal inactivation** For category 1 or category 3 humidifiers, the duration of audio paused or alarm paused for the alarm conditions required by this document shall not exceed 120 s without operator intervention.	Complies	Pass
211	**Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment**		
211.10.1.1	**General requirements for mechanical strength**	Not applicable	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

Summary of contents:

The equipment has been tested according to standard ISO 80601-2-74:2021 Medical electrical equipment Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

All applicable tests according to the above specified standard(s) have been carried out.

This test report comprises 31 pages of Test Report including the Annexure 'A' showing the pictures of the Product and the Annexure 'B' Terms and Conditions of this Test Report.

For Astute Labs Pvt. Ltd.,

Authorised Signatory

ASTUTE LABS PVT. LTD. INDIA

Annexure 'A'
Photographs of Product

Front side

Rear side

Left Side

Right Sid

Accessories

Nasal Cannula

Breathing Circuit

Needle

Oxygen Tube

Power Cord

Oxygen Flowmeter

Humidification Chamber

Annexure 'B'

Terms and Conditions:

1. This Test Report is prepared by Astute Labs Pvt. Ltd., Pune, hereinafter referred to as the "Laboratory", upon a request from the applicant as mentioned on the page 1 of the report under the title "Applicant", hereinafter referred to as the "Applicant". The Applicant submitted a product for tests as conducted in the Report, as mentioned on the page 1 of the report under the title "Model/type reference", hereinafter referred to as the "Product".
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11. The tests are conducted in the presence of the Applicant's representative who is technically competent and the Product under tests is operated according to the Operations Manual and also by consulting the applicant's representative.
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