

Test Report No.: _____

TEST REPORT

Astute Labs Pvt. Ltd

Corporate Office: #306, 4th Floor, Sai Apex, Near Datta Mandir, Viman Nagar,
Pune-411014, Maharashtra, India.

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

Phone: 020-65008994


www.astutelabs.net

TEST REPORT

IEC 60601-1:2005+AMD1:2012+AMD2:2020

Medical electrical equipment

Part 1: General requirements for basic safety and essential performance

Report reference No.	2205003
Approved by (+ signature)	Kunal Deshpande 
Date of issue	10.05.2022
Testing laboratory	Astute Labs Pvt. Ltd.
Address	Office # 01A, B Wing, Siddhesh Optimus, Opp.Lunkad 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	Atreya Innovations Pvt Ltd
Address	Office no 1, 3 rd floor, City Center, Hinjewadi Phase I, Pune 411057.
Standard	IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
Test procedure	According to IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
Procedure deviation	N/A
Non-standard test method	N/A
Discipline/ Group	Electronics / Safety Testing Facility
Type of test object	Nadi Parikshan Device
Trademark	Nadi Tarangini
Model/type reference	Nadi Parikshan Device
Manufacturer	Atreya Innovations Pvt Ltd
Address	Office no 1, 3 rd floor, City Center, Hinjewadi Phase I, Pune 411057.
Ratings	Input: 1) Supplied by AC mains: 100-240VAC, 50/60Hz, 250mA, or 2) Supplied by external adapter: NA, or 3) Supplied by internal electric power source: 3.7 VDC, 1800mAh









Report Modifications Summary

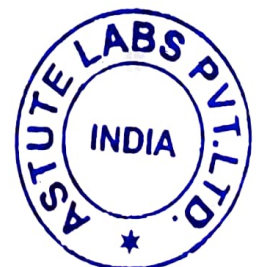
The following changes were made to this report. If none listed in the below table, this report is the originally issued report.

Date Modified	Modification	Modified By
	None	



COPY OF MARKING PLATE

 Manufactured by Atreya innovations Private Limited Address: Office no 1, 3 rd floor, City Center, Hinjewadi Phase 1, Pune 411057.	 Date of Manufacturing if applicable. February 2022	Input Supply: 100-240VAC 250mA , 50- 60Hz,
Sr. No. NT000581	Model / Type : Nadi Tarangini	
	 Refer manual optional	



GENERAL INFORMATION	
Condition of the EUT.....	EUT received in working condition / non-working condition
Test item particulars (see also clause 6):	
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 :	N/A
Options included	N/A
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	
Testing	
Date of receipt of test item(s).....	11.04.2022
Dates tests performed.....	12.04.2022 to 07.05.2022

General product information and considerations: Nadi Tarangini auscultates subtle changes in overall health parameters based on Vatta, Pitta, Kapha (Tridosha) diagnostics. Nadi tarangini is an ideal fit for doctors who are practitioners of Ayurveda, homeopathy, Naturopathy, acupuncture & alternative traditional medicines to unmask really helpful information about the inner health of their patients. It would also be helpful for wellness centers, Gym trainers, Yoga trainers, health coaches & nutritionists to understand their users completely and design a personalized wellness plan for them accordingly.



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Table: Insulation Diagram							
Pollution degree		2					
Overvoltage category		2					
Altitude		≤ 2000					
CTI		IIIB					
Area	Number and type of Means of Protection: MOOP, MOPP	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
A	BI	230	2.5	2.0	>5	>4	Pass
B	DI	3.7	1.7	0.8	>4	>3	Pass
C	DI	3.7	1.7	0.8	>4	>3	Pass

INSULATION DIAGRAM CONVENTIONS

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

1. All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
2. Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
3. Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
4. Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.



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4.11 TABLE: Power input						
Operating condition	Voltage V AC	Frequency Hz	Current mA	Power VA	Watts W	Remarks
Stable	100	50	44.5	9.20	3.55	Pass
Stable	170	50	43.0	9.91	3.68	Pass
Stable	240	50	42.5	10.75	3.83	Pass
Working condition	100	50	44.9	9.30	3.55	Pass
Working condition	170	50	43.3	9.96	3.68	Pass
Working condition	240	50	42.6	10.77	3.83	Pass

Supplementary information: At the time of charging

5.7 Humidity preconditioning treatment		Pass
Temperature	25°C	
Humidity	93%	
Time	48 Hr	

5.9.2 TABLE: Determination of ACCESSIBLE parts			
Location	Determination method (NOTE1)	Comments	Remark
Front display	Visual; Rigid test finger; Jointed test finger; Test hook	No electrical parts are accessible	Pass
Back side of the unit	Visual; Rigid test finger; Jointed test finger; Test hook	No electrical parts are accessible	Pass

Supplementary information:
NOTE 1 - The determination methods are: visual; rigid test finger; jointed test finger; test hook.



7.1.2	TABLE: Legibility of Marking		Pass
Markings Tested		Ambient Illuminance (lx)	Remarks
Outside Markings (Clause 7.2)		100-1500	The markings can be correctly read from the viewpoint.
Inside Markings (Clause 7.3)		100-1500	The markings can be correctly read from the viewpoint.
Controls & Instruments (Clause 7.4)		100-1500	The markings can be correctly read from the viewpoint.
Safety Signs (Clause 7.5)		100-1500	The markings can be correctly read from the viewpoint.
Symbols (Clause 7.6)		100-1500	The markings can be correctly read from the viewpoint.
Supplementary information: Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20) and is able to read N6 of the Jaeger test card in normal room lighting condition (~500lx), reads marking at ambient illuminance least favourable level in the range of 100 lx to 1,500 lx. The ME EQUIPMENT or its part was positioned so that the viewpoint was the intended position of the OPERATOR or if not defined at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.			

7.1.3	TABLE: Durability of Marking Test	
Marking tested	Remarks	
Address of the manufacturer	Pass	
Supply voltages	Pass	
Serial number & model	Pass	
Attention, consult accompanying document	Pass	
All warning and caution labels	Pass	
Supplementary information: Marking rubbed by hand, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol 96%, and then for 15 s with a cloth rag soaked with isopropyl alcohol.		



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8.4.3											TABLE: residual voltage in attachment plug
Maximum allowable voltage (V)										60	
Voltage measured (V)											
Voltage measured between:	1	2	3	4	5	6	7	8	9	10	Remarks
supply pins (pin 1 & pin 2)	0	0	0	0	0	0	0	0	0	0	Pass
line pin 1 and enclosure	0	0	0	0	0	0	0	0	0	0	Pass
line pin 2 and enclosure	0	0	0	0	0	0	0	0	0	0	Pass
pin 1 and earth pin	0	0	0	0	0	0	0	0	0	0	Pass
pin 2 and earth pin	0	0	0	0	0	0	0	0	0	0	Pass
Maximum allowable stored charge when measured voltage exceeded 60 v (μC)										45	
Calculated stored charge (mc)											
Voltage measured between:	1	2	3	4	5	6	7	8	9	10	Remarks
supply pins (pin 1 & pin 2)											N/A
line pin 1 and enclosure											
line pin 2 and enclosure											
pin 1 and earth pin											
pin 2 and earth pin											

8.4.4											TABLE: residual voltage or energy in capacitors
Maximum allowable residual voltage (V):										60 V	
Maximum allowable stored charge when residual voltage exceeded 60 V										45 μC	
Capacitor and its location	Residual voltage (V)	Time after disconnection (s)	Capacitance value (μF)	Residual energy (mJ)	Remarks						
					N/A						



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8.6.4 TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH			
Test location	Test current (A)/ Duration (s)	Maximum calculated Impedance (mΩ)	Remarks
			N/A

Supplementary information: With mains supply cord (Max. 200 mΩ)



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8.7 TABLE: leakage current (Before per condition)

Test Result

Test Element	Test Type																
IEC 60601-1 - CL2 Procedure: (1) Connect the DUT to the ESA620 as indicated in the operators manual. (2) Ensure that DUT power is On. (3) Click module setup and specify the patient leads that are to be tested. (4) Connect patient leads as indicated to the right. (5) Click Start Test to perform the safety test.	Auto Sequence																
Applied Part setup																	
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Configuration: Unused Applied Parts: Floating	Enclosure Leakage Current																
Normal Condition																	
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Result:	Value	Enclosure Leakage Current Normal Condition Unit	High Limit	Low Limit	Standard												
Normal Condition	11.6	uAAC+DC	100		IEC 60601												
Open Neutral																	
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Open Neutral, Reversed Mains	9.5	uAAC+DC	500		IEC 60601												
Patient Leakage Current																	
Configuration: Total Leakage: No Unused Applied Parts: Floating	Patient Leakage Current																
Normal Condition																	
	Patient Leakage Current Normal Condition																



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Test Element	Result:	Value	Test Type			Standard
			Unit	High Limit	Low Limit	
B(1)	B(1)	0.6	uAAC+DC	100		IEC 60601
Open Neutral						
			Patient Leakage Current Open Neutral			
B(1)	B(1)	0.9	uAAC+DC	500		IEC 60601
Normal Condition, Reversed mains						
			Patient Leakage Current Normal Condition, Reversed mains			
B(1)	B(1)	0.5	uAAC+DC	100		IEC 60601
Open Neutral, Reversed Mains						
			Patient Leakage Current Open Neutral, Reversed Mains			
B(1)	B(1)	1.0	uAAC+DC	500		IEC 60601



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8.7 TABLE: leakage current (After per condition)

Test Result

Test Element	Test Type																														
IEC 60601-1 - CL2	Auto Sequence																														
Procedure: (1) Connect the DUT to the ESA620 as indicated in the operators manual. (2) Ensure that DUT power is On. (3) Click module setup and specify the patient leads that are to be tested. (4) Connect patient leads as indicated to the right. (5) Click Start Test to perform the safety test.																															
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uAAC+DC	500																														
Patient Leakage Current																															
<i>Patient Leakage Current</i>																															
Configuration: Total Leakage: No Unused Applied Parts: Floating																															
Normal Condition																															
<i>Patient Leakage Current</i>																															
<i>Normal Condition</i>																															





Test Report

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Report No. 2205003

Fluke Biomedical Ansur Test Report

Test Element	Value	Unit	High Limit	Low Limit	Standard
Result: B(1)	0.8	uAAC+DC	100		IEC 60601
Open Neutral					
Result: B(1)	0.7	uAAC+DC	500		IEC 60601
Normal Condition, Reversed mains					
Result: B(1)	0.7	uAAC+DC	100		IEC 60601
Open Neutral, Reversed Mains					
Result: B(1)	0.8	uAAC+DC	500		IEC 60601





8.8.3 TABLE: Dielectric strength(Before per condition)				
Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Peak Working voltage (V)	Test voltage (V)	Remarks
Mains to Earth				N/A
Mains to Body	1 MOOP	230	1500	Pass
Mains to Applied part	2 MOPP	230	4000	Pass

8.8.3 TABLE: Dielectric strength(After per condition)				
Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Peak Working voltage (V)	Test voltage (V)	Remarks
Mains to Earth				N/A
Mains to Body	1 MOOP	230	1500	Pass
Mains to Applied part	2 MOPP	230	4000	Pass

8.8.4.1 TABLE: Resistance to heat - Ball pressure test of thermoplastic parts			
Allowed impression diameter (mm)	≤ 2 mm		
Force (N)	20		
Test Time (Hr)	1		
Part/material	Test temperature (0C)	Impression diameter (mm)	
Enclosure	70	0.8	

9.4.2.1 TABLE: Instability—overbalance in transport position		
ME Equipment preparation	Test Condition (transport position)	Remarks
Nadi Tarangini	Transport position	The equipment did not overbalance



9.4.2.2	TABLE: Instability—overbalance excluding transport position		
ME Equipment preparation	Test Condition (excluding transport position) Test either 5 ° incline and verify Warning marking or 10 ° incline)	Remarks	
Nadi Tarangini	Excluding transport position	The equipment did not overbalance	

11.1.1	TABLE: normal temperature				
Supply voltage: 90 & 264 VAC		Test Condition: As per user manual			
Ambient temperature: 25°C					
Working Voltage	Measuring location	Measured temperature [°C]	Limits	Table	Remarks
90	PCB	40	105	22	Pass
	ON/OFF switch	38	60	23	Pass
	Enclosure	39	48	23	Pass
	Battery	51	105	22	Pass
	Sensor- V	37	43	24	Pass
	Sensor- P	37	43	24	Pass
	Sensor- K	38	43	24	Pass
	Control card IC	45	105	22	Pass
264	PCB	43	105	22	Pass
	ON/OFF switch	41	60	23	Pass
	Enclosure	42	48	23	Pass
	Battery	55	105	22	Pass
	Sensor- V	39	43	24	Pass
	Sensor- P	38	43	24	Pass
	Sensor- K	39	43	24	Pass
	Control card IC	49	105	24	Pass



Clause	Name of Test	Test conditions	Observed results/Remarks
15.3	TABLE: Mechanical Strength tests		
15.3.2	Push Test	Force = 250 N \pm 10 N for 5 s	No damage observed
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g \pm 25 g) falling from a 1.3 m	No damage observed
15.3.4.1	Drop Test (hand-held)	Free fall height (m) =	N/A
15.3.4.2	Drop Test (portable)	Drop height (cm) =5	No damage observed
15.3.5	Rough handling test	Travel speed (m/s) = 0.8m/s	N/A
15.3.6	Mould Stress Relief	7 h in oven at temperature ($^{\circ}$ C) =70	No deformation on enclosure

Summary of contents:

The equipment has been tested according to standard IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment Part 1: General requirements for basic safety and essential performance.

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

This test report comprises 24 pages of Test Report including the Annexure 'A' showing the pictures of the Test set-up and the Annexure 'B' Terms and Conditions of this Test Report.

For Astute Labs Pvt. Ltd.,



Authorised Signatory



Annexure 'A'

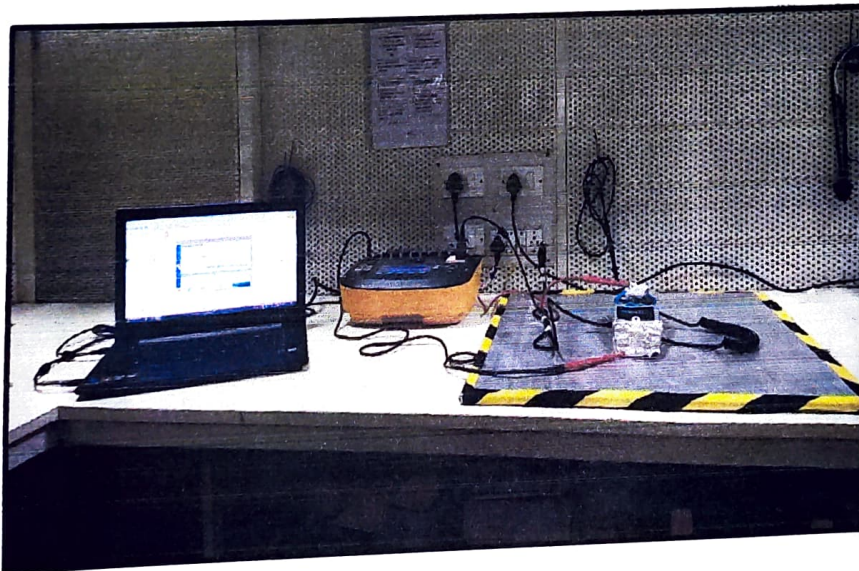
Photographs of the test set up.

Note : The photographs are provided to explain the set up of the test. For safety reasons it is not possible to photograph the actual test results.

Power Input



Leakage current



Test Report

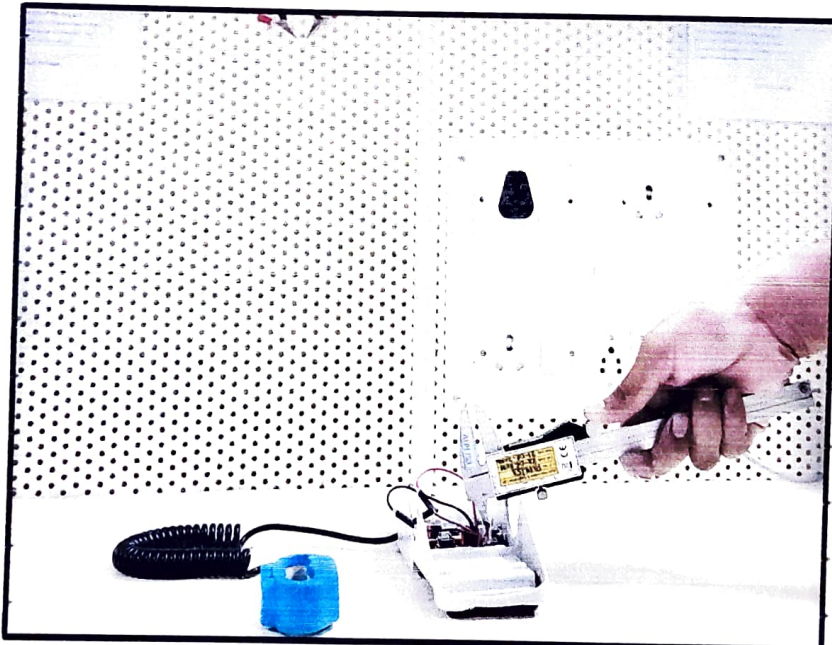
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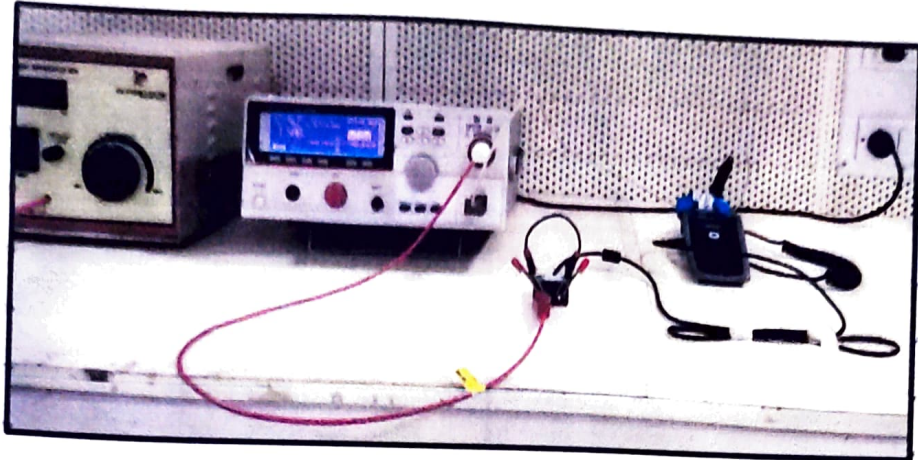
Temperature monitoring



Creepage & Clearance



Dielectric strength –Mains to body

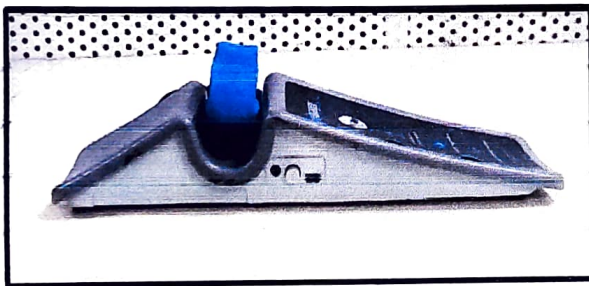


Product Photograph

Top Side



Left Side



Right Side



Inside



Terms and Conditions:**Annexure 'B'**

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".
2. This Test Report issued by the Laboratory, is a record of tests conducted on the Product submitted by the Applicant for testing and the results thereof and does not apply to any other items even though declared to be identical.
3. This test report if required to be reproduced for any purpose, commercial or otherwise, a prior permission should be taken for the same from the Laboratory.
4. The Laboratory shall not be liable / responsible for any liquidated, un-liquidated damages, costs, expenses, losses of whatsoever nature arising out of the, or relating to or use of or reliance on the test report.
5. The results contained herein apply only to the particular sample/s tested and to the specific tests carried out, as detailed in this Test Report.
6. The issuing of this Test Report does not indicate any measure of Approval, Certification, Supervision, Control or Surveillance by the Laboratory of any product.
7. The Laboratory shall not be liable and or responsible for any unauthorised changes, alterations, modifications made by any person including the Applicant, to the Test Report.
8. The Test Results reported in this report are valid at the time of and under the stated conditions of the measurements.
9. The Laboratory does not guarantee the recognition or acceptance of the report by any specific certification / notified body or organization.
10. The Applicant has identified the applicable standards for the Product and also classified the Product according to those standards. The Laboratory has conducted the tests according to the instructions and the classifications of the Product received from the Applicant. The Laboratory is not responsible for the correctness of the classification of the Product according to the relevant standards.
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.
12. This Test report does not and shall not be used as a basis for any performance or suitability of the Products for any purpose or for any other commercial purpose. The Laboratory shall not be liable for any liquidated, un-liquidated damages, costs, expenses of whatsoever nature arising out of use or non-performance / under performance or failure of the Product.
13. The Test Report is non-transferable. This report shall become void in case of change in the majority ownership and or constitution of the Applicant.
14. The Laboratory relies upon the Applicant wherever the Applicant claims that the Applicant has conducted part of the tests in-house or at a third party test house. In that case the remark in the Report says "Tested Separately". The Laboratory is not responsible for the correctness or availability of such test results.
15. The Test Report shall be void if the Laboratory does not receive the full payment towards the testing of the Product in the stipulated time.
16. This Test Report does not guarantee or warranty as to ownership or title or merchantability of the Product, its quality, material used for manufacture or manufacturing techniques employed by the Applicant or assure fitness of the Product for any particular use.
17. Any or all disputes arising out of this Test Report shall be subject to the jurisdiction of Courts at Pune only at the exclusion of all other courts, forums, etc.
18. Reports are submitted to clients on a confidential basis. No reference to the work, the results, or to Astute Labs in any form of advertising, news release, or other public announcement may be made without our written authorization. Test results are applicable only to the samples being tested within the limits of the testing procedures identified and are not necessarily indicative of the characteristics of any other samples from the same or other lots. Astute Labs Pvt Ltd shall not be liable under any circumstances for any amount in excess of the cost of the test performed.