



# TEST REPORT



TUV India Pvt. Ltd,  
Anjani Palladium, 203 & 204, Second Floor And Mezzanine Floor,  
104b, Survey No.126/1, Baner Main Road, Baner, Pune 411045, Maharashtra, India.  
Tel No: +(91) 20-67113113  
Website : [www.tuv-nord.com](http://www.tuv-nord.com)

Report No: TUV/PTL/20-21/EMC/0033

Page 1 of 22

ULR NO: TC523720000000087F

1. Job Order No. : 8118675400
2. Sample ID : TUV/PU201109-005
3. Item Receipt date : 09/11/2020
4. Test Start Date : 23/11/2020 Test Completion Date : 23/11/2020
5. Test Carried out at : **M/s., TUV India Private Limited**  
Anjani Palladium, 203 & 204, Second Floor And Mezzanine Floor, 104b, Survey No.126/1, Baner Main Road, Baner, Pune 411045, Maharashtra, India.
6. Description and Identification of Item:  
Nomenclature : ERVA-Emergency Respiratory Ventilation Apparatus  
Model No. : ERVA - V1  
Serial No. : 3010202001  
Make : Vexma Technologies Pvt. Ltd.  
Quantity : 01
7. Condition of item when received : Good
8. Purpose of testing : EMC Characteristics
9. Test Results : Pass
10. Declaration of Conformity : Declaration of conformity of results is based on as per standard limits or criteria.
11. Applicable Standards : As per IEC 60601-1-2:2014  
Also see section 16.

Tested by:	Reviewed by:	Approved by:
Priyanka Patil (Test Engineer)	Rahul Bhintade (Test Engineer)	Vipul Agrawal (Sr. Test Engineer)
Date: 28/12/2020	Date: 28/12/2020	Date: 28/12/2020



TC-5237

# TEST REPORT



<b>TUV India Pvt. Ltd,</b> Anjani Palladium, 203 & 204, Second Floor And Mezzanine Floor, 104b, Survey No.126/1, Baner Main Road, Baner, Pune 411045, Maharashtra, India. Tel No: +(91) 20-67113113 Website : <a href="http://www.tuv-nord.com">www.tuv-nord.com</a>	
<b>Report No:</b> TUV/PTL/20-21/SFTY/0070	<b>Date of issue:</b> 28.12.2020
<b>ULR No:</b> TC523720000000093F	

1. **Job Card No.** : TUV/20-21/SFT/0060
2. **Job Order No.** : 8118675400
3. **Sample ID** : TUV/PU201109-005
4. **Service Requested by** : VEXMA TECHNOLOGIES PVT. LTD  
Mona Tiles Compound, Near Chaani Circle, Chhani Road,  
Vadadora-390002
5. **Report Issued to** : VEXMA TECHNOLOGIES PVT. LTD  
Mona Tiles Compound, Near Chaani Circle, Chhani Road,  
Vadadora-390002





<b>Issued By:</b>
<b>Sneha Mandve / (Jr. Officer)</b>
<b>Date: 28.12.2020</b>



**TUV India Private Limited**

Anjani Palladium, 203 & 204,  
 Second Floor And Mezzanine  
 Floor, 104B, Survey No.126/1,  
 Baner Main Road, Baner,  
 Pune 411045,  
 Maharashtra, India  
 CIN  
 U74140MH1989PTC052930  
 Tel. : 020 6647 7000  
 Toll Free : 1800-209-0902  
 Email : [pune@tuv-nord.com](mailto:pune@tuv-nord.com)  
 Website : [www.tuv-nord.com/in](http://www.tuv-nord.com/in)

<b>IEC 60601-1</b> <b>Medical electrical equipment</b> <b>Part 1: General requirements for basic safety and essential performance</b>	
Report Reference No..... :	TUV/PTL/20-21/SFTY/0070
Date of issue .....	28/12/2020
Total number of pages .....	18
ULR No.....:	TC523720000000093F
<b>Test specification:</b>	
Standard .....	IEC 60601-1:2005+AMD1:2012
Test procedure..... :	As Above
Non-standard test method.....:	NA
Test Report Form No..... :	IEC60601_1
Test Report Form Originator .....	TUV-005
Master TRF .....	Dated 04.02.2020
<b>General disclaimer:</b>	
<ol style="list-style-type: none"> <li>1. The Released Test Report/s relates ONLY to the specific sample/s submitted for testing and under the stated conditions</li> <li>2. Any corrections/erasures invalidate the Test Reports. TUV India does not accept any liability whatsoever for the tampering or any unlawful or inadvertent alteration of documents that have been handed over to the Customer.</li> <li>3. Any discrepancy in the Test report should be brought to the notice of TUV India within 1 (One) Month from the date of issue unless the query raised by regulatory or accreditation body.</li> <li>4. Test Reports / Certificates or/and any associated attachments shall NOT be copied/reproduced, except IN FULL, without the prior written consent of TUV India.</li> <li>5. All services rendered by TUV India will be treated as strictly Confidential.</li> <li>6. TUV India will respond to clarifications requested by the Customer for a maximum period of 1 (One) Month from the date of receipt by the Customer. Samples will not be retained by TUV India after testing is completed or as applicable regulatory requirements</li> </ol>	

Test item description..... :	ERVA (Emergency Respiratory Ventilation Apparatus)	
Trade Mark..... :		
Model/Type reference..... :	ERVA-1	
Ratings..... :	INPUT: 100Vac -250Vac Current Rating: Min 3.5A@100VAC, Max1.8A@250VAC	
<b>Testing procedure and testing location:</b>		
<input checked="" type="checkbox"/> Testing Laboratory:	TUV India Private Limited	
Testing location/ address .....	ANJANI PALLADIUM, 203 & 204, SECOND FLOOR AND MEZZANINE FLOOR, 104B, SURVEY NO.126/1, BANER MAIN ROAD, BANER, PUNE 411045, MAHARASHTRA, INDIA	
Tested by (name, function, signature)..... :	Mr. Mayur Ramteke (Test Engineer)	
Approved by (name, function, signature) .. :	Mr. Pratik lavalekar (Test Engineer)	 



<b>List of Attachments (including a total number of pages in each attachment):</b>	
<b>1. Attachment- Photos: EUT Photographs – 2 Pages (Page No. 17 to Page No.18)</b>	
<b>Summary of testing</b>	
<b>Tests performed (name of test and test clause):</b> Cl. 4.11 Power input Cl. 8.4.3 ME equipment intended to be connected to a power source by a plug (Residual voltage in attachment plug) Cl. 8.6.4 Impedance and current-carrying capability (Impedance and current-carrying capability of protective earth connections) Cl. 8.7.4.5 Measurement of Earth leakage current Cl. 8.7.4.6 Measurement of Touch current Cl. 8.7.4.7 Measurement of Patient leakage current Cl. 8.7.4.9 ME equipment with multiple Patient connections Cl. 8.8.3 Dielectric Strength Cl. 8.9.4 Measurement of Creepage distances and Air Clearances Cl. 11.1 Excessive Temperatures in ME equipment Cl. 11.6.5 Ingress of water or particulate matter into ME equipment or ME systems Cl. 11.8 Interruption of the power supply/ supply mains to ME systems Cl. 15.3.2 Push test Cl. 15.3.3 Impact test	<b>Testing location:</b> <b>TUV India Private Limited</b> ANJANI PALLADIUM, 203 & 204, SECOND FLOOR AND MEZZANINE FLOOR, 104B, SURVEY NO.126/1, BANER MAIN ROAD, BANER, PUNE 411045, MAHARASHTRA, INDIA
<b>Summary of compliance with National Differences</b>	
<input checked="" type="checkbox"/> The product fulfils the requirements of IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012	
<b>ELECTRONIC DISCIPLINE:          SAFETY TESTING FACILITY</b>	

Copy of marking plate:

**Device:-** ERVA- Emergency Respiratory  
Ventilation Apparatus

**Power Supply**

Input : 100 VAC- 250 VAC

Current Rating:-

Min 3.5A@100VAC, Max1.8A@250VAC

Battery : Li- Ion Battery

Serial Number: 3010202001

Model No. : ERVA - V1

**Manufactured By :**

Vexma Technologies Pvt Ltd

Monatiles Compound,

Old Channi Road, Vadodara

Gujarat 390002

Ph : 0265 2775477




[info@vexmatech.com](mailto:info@vexmatech.com)

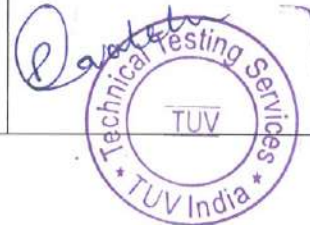


**TUV India Private Limited**

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Floor, 104B, Survey No.126/1,  
Baner Main Road, Baner,  
Pune 411045,  
Maharashtra, India  
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Tel. : 020 6647 7000  
Toll Free : 1800-209-0902  
Email : [pune@tuv-nord.com](mailto:pune@tuv-nord.com)  
Website : [www.tuv-nord.com/in](http://www.tuv-nord.com/in)

<b>ISO 80601-2-80</b> <b>Medical electrical equipment</b> <b>Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency</b>	
Report Reference No..... :	TUV/PTL/20-21/SFTY/0070-1
Date of issue .....	28/12/2020
Total number of pages .....	17
<b>Test specification:</b>	
Standard .....	ISO 80601-2-80:2018
Test procedure.....	As Above
Non-standard test method.....	NA
Test Report Form No.....	ISO80601_2_80
Test Report Form Originator .....	TUV-028
Master TRF .....	Dated 04.02.2020
<b>General disclaimer:</b>	
<ol style="list-style-type: none"><li>1. The Released Test Report/s relates ONLY to the specific sample/s submitted for testing and under the stated conditions</li><li>2. Any corrections/erasures invalidate the Test Reports. TUV India does not accept any liability whatsoever for the tampering or any unlawful or inadvertent alteration of documents that have been handed over to the Customer.</li><li>3. Any discrepancy in the Test report should be brought to the notice of TUV India within 1 (One) Month from the date of issue unless the query raised by regulatory or accreditation body.</li><li>4. Test Reports / Certificates or/and any associated attachments shall NOT be copied/reproduced, except IN FULL, without the prior written consent of TUV India.</li><li>5. All services rendered by TUV India will be treated as strictly Confidential.</li><li>6. TUV India will respond to clarifications requested by the Customer for a maximum period of 1 (One) Month from the date of receipt by the Customer. Samples will not be retained by TUV India after testing is completed or as applicable regulatory requirements</li></ol>	

Test item description..... :	ERVA (Emergency Respiratory Ventilation Apparatus)	
Trade Mark..... :		
Model/Type reference..... :	ERVA - V1	
Ratings..... :	Input: 100VAC – 250VAC, Current rating: Min 3.5A@100VAC, Max.1.8A@250VAC, Battery: Li-ion battery,	
<b>Testing procedure and testing location:</b>		
<input checked="" type="checkbox"/> Testing Laboratory:	TUV India Private Limited	
Testing location/ address .....	ANJANI PALLADIUM, 203 & 204, SECOND FLOOR AND MEZZANINE FLOOR, 104B, SURVEY NO.126/1, BANER MAIN ROAD, BANER, PUNE 411045, MAHARASHTRA, INDIA	
Tested by (name, function, signature)..... :	Mr. Mayur Ramteke (Test Engineer)	
Approved by (name, function, signature) .. :	Mr. Pratik lavalekar (Test Engineer)	





<b>List of Attachments (including a total number of pages in each attachment):</b>	
<b>1. Attachment- Photos: EUT Photographs – 2 Pages (Page No. 16 to Page No. 17)</b>	
<b>Summary of testing</b>	
<b>Tests performed (name of test and test clause):</b> CI. 20.7.2.101 Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts CI. 201.7.2.4.101 Additional requirements for ACCESSORIES CI. 201.7.2.13.101 Additional requirements for physiological effects CI 201.7.4.3 Unit of Measure CI 201.7.9.2.2.101 Additional requirements for warnings and safety notices CI 201.7.9.2.12 Cleaning, disinfection, and sterilization CI 201.11.6.5.101 Additional requirements for ingress of water or particulate matter into ME EQUIPMENT or ME SYSTEM CI 201.11.8.101.1 ALARM CONDITION CI 201.11.8.101.2 Alternative power supply/supply mains	<b>Testing location:</b> <b>TUV India Private Limited</b> ANJANI PALLADIUM, 203 & 204, SECOND FLOOR AND MEZZANINE FLOOR, 104B, SURVEY NO.126/1, BANER MAIN ROAD, BANER, PUNE 411045, MAHARASHTRA, INDIA
<b>Summary of compliance with National Differences</b>	
<input checked="" type="checkbox"/> The product fulfils the requirements of ISO 80601-2-80:2018101	

Copy of marking plate

**Device:- ERVA- Emergency Respiratory  
Ventilation Apparatus**

**Power Supply**

Input : 100 VAC- 250 VAC

Current Rating:-

Min 3.5A@100VAC, Max1.8A@250VAC

Battery : Li- Ion Battery

Serial Number: 3010202001

Model No. : ERVA - V1

**Manufactured By :**

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Monatiles Compound,

Old Channi Road, Vadodara

Gujarat 390002

Ph : 0265 2775477

[info@vexmatech.com](mailto:info@vexmatech.com)