



## Medical Device Centre of Excellence

TÜV Rheinland India Operates Testing Facilities as per National and International Standards.



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Precisely Right.



# State-of-the-Art Biomaterial Testing Services

## Testing According to National and International Standards:

TÜV Rheinland works in alignment with the standard protocols set by national and international standards for biomaterial.

Our biomaterials testing services include Physio-Chemical Evaluation, Histopathological Evaluation, Sterility Evaluation, and Chromatography based assessment of materials.

### Physiochemical Evaluation:

Physio-chemical evaluation helps to understand the biochemical nature of the material intended to be implanted including identification, quantification, degradability, 3D evaluation and topographical characterization. Our lab is equipped with top-end equipment such as Micro-Computerized Tomography, Scanning and Transmission Electron Microscopy (SEM and TEM), Raman Spectrophotometer, Confocal Microscope, Confocal-Surface Profiler, and several more.

### Histopathological Evaluation:

Standard test methods are used to understand the histopathology of samples collected, prior to and after implantation of any device or implant. Examination of serum, grafts, and any related material are conducted in our well-equipped histopathology laboratory. Our equipment includes Tissue Processor, Microtome, Tissue Embedding System, Autostainer, Trinocular Microscopy, Flow Cytometer, Biochemistry Analyzer and Haematology Analyzer.

### Sterility Evaluation:

Sterility evaluation is one of the crucial steps that a device or implant has to pass through. Our Biosafety Level-III facility helps to evaluate product safety in terms of parameters such as sterility, stabilizability and bio-burden on the device or implant.

Our Biosafety Level II facility is well equipped with a full range of microbiological equipment to handle Sterility Evaluation not only of medical devices but also related to water, waste water and API segments.

### Other Testing Facilities:

TÜV Rheinland has established a world-class Centre of Excellence located in the Andhra Pradesh Medical Tech Zone (AMTZ), Visakhapatnam. This one-stop-solution facilitates manufactures to test and certify their products and thereby expand their product reach into new markets. Apart from the Biomaterial Testing Laboratory, our Centre of Excellence also provides testing services for Accelerated Aging, Package Validation, Electrical and Environmental, Radiation Safety, Acoustic & EMI/ EMC. Our Laboratory includes Semi Anechoic Chamber (10 metres and 3 metres), Humidity Chambers, Thermal Shock, and High Ramp Chambers, Multi-Torsion Tester, Torque Testing Machine, High-speed Pneumatic Impact Tester, and several more.

### Biomedical Devices or Implants:

The Biomaterial Testing Laboratory (BTL) has been established to test the diversity of biomedical devices and implants so that it can help our stakeholders increase their market share. The BTL can work in association with innovators for customized testing methods.

Biomaterial applications listed below can be tested in our BTL as per stakeholder requirements:

- Bone Joint Implants
- Bone Plates and Cement
- Intraocular Lens
- Contact Lens
- Heart Valves
- Vascular Grafts
- Breast Implants
- Skin Contact Materials
- Hydrogels
- Silicone Rubber
- Stainless Steel
- Nanoparticle Material
- Alloys
- Cellulose
- Coating Material
- Hydroxyapatite
- Collagen



Our specialized analytical testing facilities include the following:

#### Chromatography:

Our high throughput chromatography facility establishes proof of identity for your biomaterial.

Our specialized material analysis services render:

- Analysis of a complex mixture of organic and inorganic compounds through High-Performance Liquid Chromatography (HPLC)
- Identification of unknown materials with the help of FTIR Spectrophotometer, FT-Raman and GC-MS
- Quantification and Speciation of metals by ICP-MS
- Determination of relative molecular weight by GPC (Gel Permeation Chromatography)

#### Confocal Microscopy:

Our high-end Optical Microscopy facility enables visualization deep within both living and fixed cells. Laser Scanning Confocal Microscope captures live cells without any damage, helps tissue engineering, and regenerative medicine. Our state-of-the-art facility is equipped with a wide field Confocal Microscope for surface profiling.



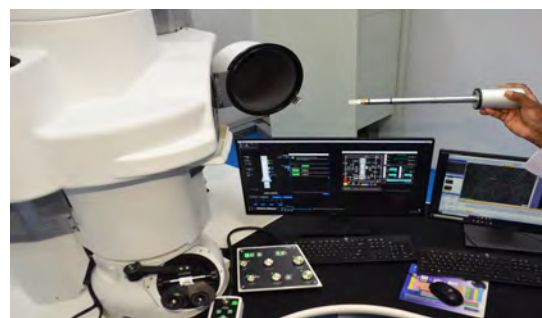
#### Transmission Electron Microscope (TEM):

It renders atomic-level imaging solutions ranging from the cellular level to protein and viruses.

Transmission Electron Microscope (TEM) with Cold Field Emission Gun, EDS and STEM helps to analyze structural arrangement upto the micro-molecular level.

Our Electron Microscope analysis renders:

- Local Structures and Morphology
- Dispersion of Multicomponent Polymers
- Cross-section and Crystallization of Metals and Alloys
- Microstructure of Composite Materials
- Elements of samples using EDS
- Electron Diffraction
- Nanoparticle Size Distribution





**Scanning Electron Microscope (SEM):**

Ultrastructural microscopic procedures enable the visualization of unique details of the biomaterial. Our new age Scanning Electron Microscope (SEM) with Energy Dispersive X-ray Spectrophotometer (EDS) images can examine high-moisture biological samples with elemental footprints.



Biomaterials that can be tested in our Ultra Microscopic facility include:

- Hydrogels
- Silicone Rubber
- Stainless Steel
- Nanoparticle Material
- Alloys
- Cellulose
- Coating Material
- Hydroxyapatite
- Collagen

**Raman Spectrophotometer**

Our latest version of the DXR Raman Microscope gives you true confocal depth profiling abilities, enabling you to look for evidence of inclusions or impurities and characterize multi-layer polymer films.

Our DXR Raman Microscope renders:

- Rapid and non-destructive sample analysis
- No sample preparation is required
- No water interference – easy to measure aqueous samples
- Easy access to low vibrational frequencies, making it easy to analyze inorganic molecules
- Polymers – inclusions and gel defects, weathering effects, tie layers in laminates and crystallinity
- Pharmaceutical – polymorphs, particulate contaminants, and diffusion studies
- Nanotechnology – characterize graphene, CNTs, DLC coatings, and other nanostructures

**Micro Computer Tomography:**

Micro-CT is a 3D X-ray imaging system on a small scale with high resolution, and is essentially a 3D microscope.

Our specialized material analysis services render:

- Reliable measurements without any detours
- X-ray once, evaluate anytime
- Metrological competence in all components
- Metrological Examination
- Volume Fractions and Fraction analysis
- Distance Measurements
- Composite Material examination such as Carbon Fiber, Polymer Mixes, Bone Implants, Dental Implants and Electrical aids

**Our Medical Textile Testing Services:**

TÜV Rheinland provides testing services for Protective Face Masks which comply with national and international standards including Indian standards such as IS 16289 for surgical masks alongside of EN 14683 and ASTM F2100. TÜV Rheinland’s state-of-the-art Biomaterial Testing Laboratory ensures the safety and quality of Protective Cloths, Face Masks, Surgical Coveralls and COVID-19 Coveralls remain uncompromised.

We provide solutions for three distinctive types of face masks - Surgical, Nonsurgical and Nonmedical Masks along with Surgical Coveralls and Protective Coveralls. Our multi disciplinary facility at Andhra Pradesh MedTech Zone- Visakhapatnam, India undertakes over twenty EN/IS/ASTM/ ISO standards for testing.

Our solutions range from product and packaging testing to assessments on Labelling, Flammability, Bacterial Filtration Efficiency, Particulate Filtration Efficiency, Splash Blood Resistance, Breathability and many more.

TÜV Rheinland’s Face Mask Testing Laboratory is a one-stop-solution for face mask manufacturers. Our global network of PPE specialists and accredited laboratories can ensure the compliance of face masks and PPE products with testing and certification requirements.



# EMC Testing Services

## Ensuring Compliance for Medical and Non-Medical Products.

### Electromagnetic Compatibility

TÜV Rheinland's Medical Device Centre of Excellence at Andhra Pradesh MedTech Zone (AMTZ), Visakhapatnam is a one-stop-shop for all Pre Compliance/ Full Compliance Testing for Medical and Non-medical product categories. Our comprehensive Electromagnetic Compatibility (EMC) testing and certification services will help you to efficiently meet regulatory requirements and increase global market access for your medical devices.

Our world-class EMI EMC Test Laboratory is equipped with 10 metre and 3 metre Anechoic Chambers to support customers with their regulatory and non-regulatory testing requirements. The anechoic chamber housed in this facility is the largest within TÜV Rheinland globally. We are also present in Bangalore and Pune.

The below mentioned tests are performed on Medical and Non-Medical devices:

- Radiated Emission
- Conducted Emission
- Radiated Susceptibility
- Electrostatic Discharge
- Electrical Fast Transients (EFT)
- Surge
- Conducted Susceptibility
- Power Frequency Magnetic Field
- Voltage Dips and Interruptions
- Harmonics & Flicker

### Do Not Disturb and Do Not Get Disturbed

EMC directive conformity evaluation can be combined with testing according to FCC/IC, AS/NZS standards providing additional economic benefits and encompassing certification as well as design support.

### Efficient EMC Solutions

As a Notified Body and international service provider, we provide professional services for conformity assessment for CE marking. Our strengths are our laboratory infrastructure, accreditation, and global network.

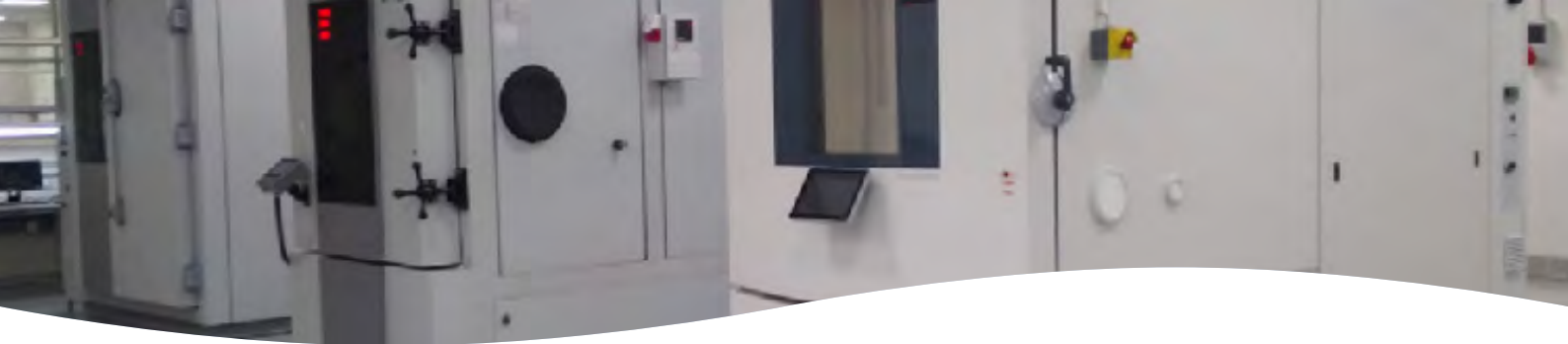
### Our Testing Capabilities

We test Medical and Non-Medical products including:

- CT Scanner
- C-Arm Scanner
- X-Ray
- Digital Mammography Devices
- Ultrasound Scanner
- Baby Incubator
- Baby Warmer
- Defibrillator
- ESG Recorders
- Dental Chairs
- Ambulance
- Power Supplies
- Infotainment and Communication Equipment
- Wireless Modules
- Network Switch
- Surveillance Cameras
- Servers and Others

### Our USPs

- Our laboratory has received ISO/IEC 17025 Accreditation from National Accreditation Board for Testing and Calibration Laboratories (NABL) and American Association for Laboratory Accreditation (A2LA)
- Testing in accordance with National and International Standards for Medical and Non-Medical products
- Adequately equipped Anechoic Chamber with supporting frequency range of 9kHz - 40GHz
- Fully automated system with turn table of 6 metre diameter and 5 ton capacity
- Dual antenna mast for reducing TAT
- A fully equipped Ambulance can be tested inside the Anechoic Chamber
- IP Camera for online streaming across the globe
- Special monitoring display to ease debugging
- Shielded room for debugging and for performing conducted emission measurements
- Well-equipped facility for ambulatory transient requirements
- One-stop-solution for all Immunity Tests as per Medical and Non-Medical product categories



# Reliability Testing Services

For safety, quality and sustainability.

Reliability tests help to accelerate the aging process of the product in order to predict its lifecycle and analyse probable future causes of failure. These tests help improve the product's design and changes can be implemented at the product developmental stage, thereby improving product quality and life while ensuring customers remain loyal to your product. Reliability tests may be performed at various stages to identify potential defects - from the prototype to the final production stage basis the manufacturer's requirement. TÜV Rheinland India, as an independent testing and certification agency, has best-in-class Reliability Testing services for a range of products including commercial, industrial, electronic sub-assemblies for consumer electronics, household, medical, lighting, and many more.

## Why TÜV Rheinland:

- Our one-of-a-kind Medical Device Centre of Excellence has an in-house Reliability Testing Laboratory equipped with Environmental Chambers, Vibration and Shock Test Equipment, Combined Shaker and Integration Test Equipment, Free Fall Drop Test Equipment, and Ingression Protection Test setup up to IP68
- We offer a one-stop-solution for all Reliability, Safety, and EMC Testing and Certifications
- Manufacturers can save time and cost by considering compliance and testing requirements during the design and development stage

## Types of Reliability Tests:

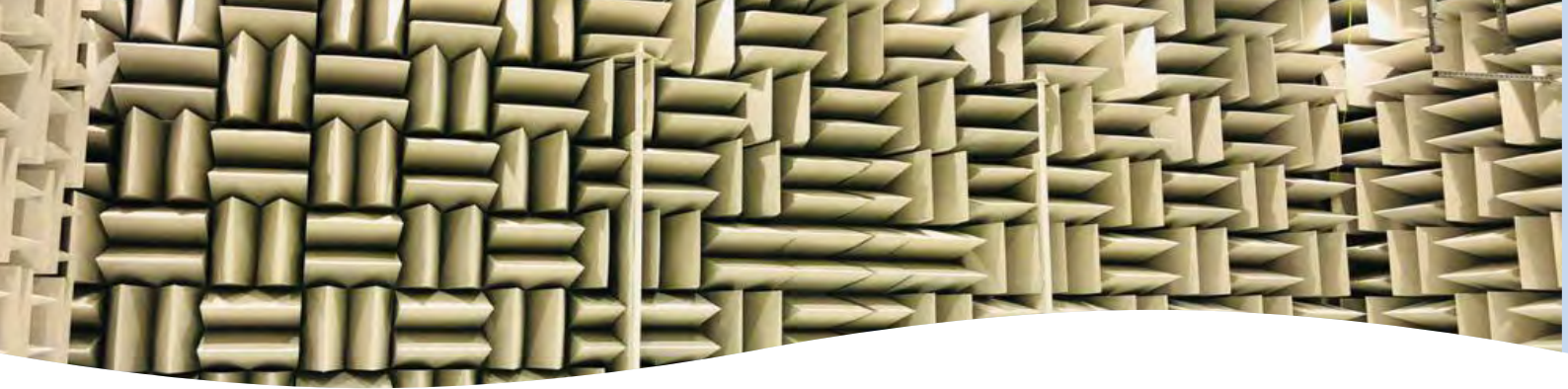
- Standard Specified Tests: Conducted as per particular IEC/ ISO/ BIS/ IS standards
- OEM Specified Tests: Conducted as per OEM's DVP
- Customer Usage Profile: Tests based on realistic expectation of customer usage
- Development Tests: Conducted during the design phase of a product:
  - Component Level Testing
  - System Level Testing
  - Environmental and Accelerated Testing
  - Shipping Test

- Manufacturing Test: Normally conducted post design finalization and release for production, where we measure the manufacturing process rather than the product
  - Functionality Testing and Burn-In
  - Extended Post-Production Testing
  - Design/ Process Change Verification

## Benefits at a glance:

- Reliability Testing helps to improve your product reliability and reduce the risk of product failure
- Enables faster time to market
- Avoid product recalls
- Increase consumer trust on your product and safeguard your brand





# Acoustics Testing and Measurement

## Overview:

A Hemi Anechoic chamber is an echo-free enclosure that is designed for acoustic analysis in a free-field environment. The unique wedge design provides an optimum level of sound absorption, for precise, repeatable acoustic measurements by allowing sound waves to propagate in all directions without any obstruction or reflection.

## Our Capabilities:

TÜV Rheinland's one-of-a-kind in-house Acoustic Test Laboratory at Andhra Pradesh MedTech Zone, Visakhapatnam performs precision and engineering-grade testing on a wide variety of devices ranging from handheld equipment to large machines including medical devices with alarm systems such as Ventilators, Incubators, Multi-parameter Monitors and many more.

The Hemi Anechoic Chamber in the Medical Device Centre of Excellence is the only such testing chamber in India established by an international certification body that is in compliance with ISO/IEC 17025 norms.

The chamber is designed to comply with ISO 3745 Standard. The primary use of this chamber is for determining Sound Power as per ISO 3744. Real-time analysis such as Time Signal, FFT, One-Third Octave are possible and A, C & Z-weighted sound pressure level and sound power level or sound energy can also be determined within this chamber.

## Our Facility:

- Internal Size: 10m (L) x 10m (W) x 5m (H) tip to tip
- Background noise: 16dB(A)
- Lower cut-off frequency: 100Hz
- Dynamic Range: more than 110dB
- Equipment Under Test (EUT) Size: up to 3m x 3m
- Air-conditioned testing environment
- Dedicated test setup for refrigerators, frozen-food storage cabinets and food freezers
- Connectors for water, wastewater and compressed air

## Products Suitable for Acoustic Testing:

- Medical Devices
- Consumer Electronics and Household Appliances
- Electrical and Electronics Equipment
- IT and Telecommunication Equipment
- Industrial Automation and Machinery
- Automotive Assemblies and Sub-assemblies



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