

Medical Device Assessment



Eurofins Advinus along with its partner lab has put together the latest in infrastructure and a team of experts to perform the necessary safety testing for your medical device/s. We understand your need for the right balance of speed and cost with the highest quality and endeavor to develop a partnership that creates mutual success.

We offer state-of-the-art facility (2000 m²) and equipment that includes -

- Cathlab (Philips Azurion 3 M12)
- Ventilators/Physiological Monitors
- IVUS (Boston Scientific)
- OCT (St. Jude's Ilumien Optis)
- Cardiac Doppler (PHILIPS CX50)
- 2D & 3D Echo Cardiograph
- High End LEICA Microscope (LM Application suite)
- Cardio Pulmonary Bypass, Defibrillators with Synch
- SEM (JEOL 0JSM-IT500HR InTouchScope™)

The laboratories use in-house developed latest data processing systems which accept digital data in standard DICOM format for QCA and QVA using the test facility's Angiography Suite or specific formats such as 3D echo cardiography, Optical Coherence Tomography (OCT), Intravenous Ultrasonography (IVUS) etc.

To help you with your research, we now offer preclinical services for Performance, Biocompatibility & Safety Evaluation of medical devices and therapeutics (ISO 10993, ISO 25539-2: 2012 and 21 CFR 58/GLP) in the following segments –

Cardiovascular Devices -

- Cardiac rhythm/ Flow management devices (Defibrillator & Pacemaker)
- Interventional cardiac devices (Stents, Catheters & Angioplasty Balloons)
- Cardiac monitoring/ Diagnostic devices (Telemetry Systems)
- Peripheral vascular devices (Stents, Grafts & Balloon Catheters)
- Electrophysiological devices (RF ablation & Laser Catheters, 3D Mapping Systems)
- Prosthetic devices and ventricular function devices (Prosthetic Valves & VAD)

Gastrointestinal Segment Devices -

Nasogastric tubes, etc.

Genitourinary Segment Devices -

 Urinary incontinence devices (Macroplastique, urethral sling implants & nephrostomy tubes/ urinary stents)

Neurological Segment Devices -

- Neuroplast implants
- Renal denervation ablation devices, etc.

Dental Devices

- Endosteal/ endosseous, Single-stage and subperiosteal
- Dental implants

Integumentary Implant Devices/ Therapeutics

· Hemostats/ Hemosealnats and Cellular implant therapies for wound healing

Orthopaedic Segment

- Tissue engineered grafts for bone defects
- Knee replacement implants (Metal and ceramic implants, etc.)

