



## **KALAM INSTITUTE OF HEALTH TECHNOLOGY**

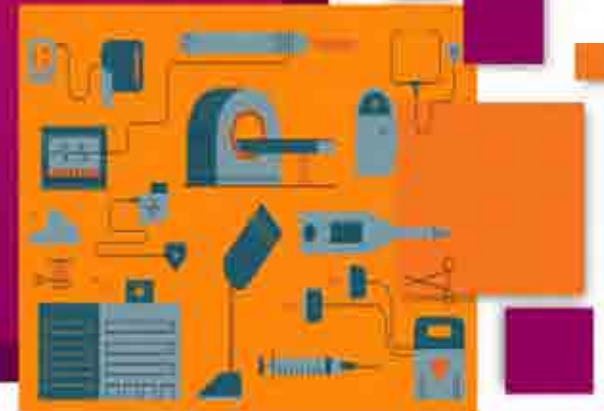
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## **Non-regulatory Innovation Potential Utility & Novelty Certificate**

**(NIPUN - निपुण)**

# SERVICES OFFERED

## 🌀 **Business Plan Realty Check**

Scrutinize the plans from every angle to ensure that the product will meet the end-user's needs

## 🌀 **Quality compliance**

To complete the design, development, manufacture and certification of medical devices

## 🌀 **Market Access Avenues**

- Health Technology Assessment
- Systematic Review/Meta Analysis
- Program efficiency model
- Uptake model

## 🌀 **Testing**

Helps in testing to comply with applicable standards

- ElectroMagnetic Interference (IEC 60601 series)
- ElectricoMagnetic Compatibility (IEC 60601-1-2)
- Electrical safety testing
- Biocompatibility (ISO 10993)
- Good Manufacturing Practices (ISO 13485)
- Software testing (IEC 62304)
- Material testing (Relavent ASTM standards)
- Radiation protection (IEC 60601-1-3)

## 🌀 **Rapid Prototyping**

Support the clients in manufacturing

- Low Volume
- High Complexity