Medistri.SA

Providing Sterilisation & Laboratory Services for the World's Most Innovative Healthcare Companies.

Development of Medical Devices Testing Stack - Medistri

🚀 **Development of Medical Devices Testing Stack**

Medistri’s in-house laboratory located at the heart of Switzerland focuses on:
- Development of Medical Devices
- Development of Pharmaceuticals
- Development of Biopharmaceuticals
- Manufacturing of Medical Devices
- Production of Pharmaceuticals

Our Laboratory works according to ISO 17025 and is accredited by the Swiss Accreditation Service (SAS). All our lab tests can be performed according to European or US pharmacopeias.

An Overview of Medistri’s Laboratory Services for the development & manufacturing of Medical Devices:

Medical device testing covers a wide variety of areas such as: Material Qualification, Ensuring Patient safety, Ensuring that the products are free of microorganisms, Sterilization Validation, Cleaning Validation or Disinfection Validation

Patient safety is predicated on the medical device’s specific structural materials and also on a comprehension of the compounds and residuals that might be produced or recognised throughout the supply chain. Medistri’s laboratory team aggregates all data, outlines findings, and recommend risk management proposals in a transparent, detailed, and precise manne — Allowing you to bring your safe product to market quickly.

🎯 To learn more about Medistri’s Laboratory’s Development of Medical Devices Testing Stack, visit on our website at www.medistri.swiss or directly contact our team at contact@medistri.swiss.

- The Medistri Team

👉Types of laboratory testing for medical devices:

✅ Biocompatibility Testing:
Biocompatibility is defined as “The ability of a device material to perform with an appropriate host response in a specific situation”. This implies that the materials that make up a medical device that is meant for interaction with or in the human body (or their degradants, leachables, or residuals) should not harm a patient's health. The ISO 10993-18 standard tests must be performed when developing a new medical device, when changing the manufacturing process or when changing materials and/or suppliers.

✅ Sterilization Validation:
Prior to beginning routine ethylene oxide sterilisation, a product with a sterile claim needs to complete a validation process to ensure the Sterility Assurance Level claimed is met according to ISO 11135. Steam Sterilisation validations are carried out in accordance with ISO 17665.

✅ Sterility Tests:
Once a sterilization method has been validated for a particular product, and the product is being manufactured, routine medical device sterility testing must be performed. These included bioburden tests, quarterly dose audits, cleaning and disinfection, and environmental monitoring, and more.

✅ Reusable Device Validations
Designers and manufacturers of reusable medical devices need to ensure that the process to make their devices safe for reuse are validated. For most devices, this includes cleaning followed by either disinfection or sterilization. It is also important to validate these processes

#Medistri
#Pharmaceutical #MedicalDevices #MedTech #BioTechnology #SterilizationServices #Laboratory Services #SterilizationValidation #SterilityTesting #BiocompatibilityTesting #Microbiology #ISO17025

Medistri’s Contract Steam Sterilisation Services:
https://www.medistri.swiss/service/our-laboratory