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SIIR offers Services to ensure Hygienic Standards for Reusable Medical Devices

Introduction

Reusable medical devices can be the primary source of spread of disease and infection.

The design of devices for reusability is particularly important in an effort to provide cost effective healthcare system Concerns and issues include the ability to safely and effectively reprocess the devices, infection prevention and control, safety of the patient and healthcare worker, environmental concerns, and effective use of resources.

Cleaning a device is the first critical step in reprocessing of any device after it has been used on a patient. Failure to remove foreign material (soil, lubricants, microorganisms, organic and inorganic materials from both outside and inside the device, can interfere with the effectiveness of subsequent disinfection and/or sterilization procedures.

Law enforces Global Standards

Safety aspects and risk associated for reprocessing of reusable medical devices has been highlighted by many regulatory authorities worldwide including U.S. Food and Drug Administration (FDA), Association for the Advancement of Medical Instrumentation (AAMI), American Society for Testing Materials (ASTM), International Organization for Standardization (ISO), Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO).

Why validation of reprocessing for reusable medical devices required in the healthcare sector?

Control of spread of infection from reusable devices is a must in every healthcare system. Infection from Cleaning, disinfecting and sterilizing technologies have also undergone significant change in the past decade, resulting in new systems and approaches that can be applied in the processing of medical devices. This has led to a greater need for the validation of processing including cleaning, disinfection and/or sterilization in order to ensure that medical devices are effectively processed. These developments have led to the need to ensure that manufacturers must use the appropriate reusable medical device.

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SIIR has one of the best facilities in India for certification of reusable medical devices under “Atma Nirbhar Bharat for reprocessing units in the healthcare sector.

SIIR is one of the pioneer research institutes available in India and South Asian countries which has the facility to assess the cleaning,disinfection & sterilization processes to validate manufacturer’s reprocessing instructions for various types of reusable medical devices. SIIR also helps to determine the appropriate level of disinfection is appropriate for devices based on their usages and fitness for purpose as per the relevant classification i.e. non-critical, semi critical or critical.

Services for healthcare Industry

Devices intended to be reprocessed must have cleaning, disinfection and/or sterilization provided with the product. These instructions for use (IFUs) will detail the right way to reprocess the device prior to use as to ensure safety of patients..

Target users and application area

Categories in reprocessing of medical devices in healthcare sector :

- ➔ Cardiovascular medical devices.
- ➔ Laparoscopic medical devices
- ➔ Gastroenterology Biopsy forceps
- ➔ Dental medical devices
- ➔ Tubular instruments
- ➔ Neonatal incubators
- ➔ General surgical medical devices
- ➔ Orthopedic external fixation devices
- ➔ Non-invasive devices
- ➔ Surgical instruments
- ➔ Endoscope and its accessories
- ➔ `NIBP cuffs and Stethoscope

What is the SIIR proposal?

SIIR offers a complete range of services for the medical devices cleaning, disinfection & validation of medical devices services to validate manufacturer’s reprocessing instructions for reusable devices in the healthcare sector.

SIIR has developed simulated conditions for cleaning and disinfection validation for the medical devices to the requirements of the manufacturers which includes inoculation methods and customized artificial test soils to create clinically relevant conditions.

Approach forward

Please feel free to contact SIIR for your needs and meet our technical experts and witness the infrastructure developed at SIIR to effectively address this area of concern. .

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