Medical Devices - Cleaning & Sterilization Validation

To ensure patient safety it is necessary to have effective and validated processes for cleaning, disinfection and sterilization of single-use and reusable medical devices as e.g. implants or surgical instruments.

The European Commission presented in Maj 2017 new regulations for medical devices, that among others stipulated that all products shall have a unique device identification (UDI) to enable full traceability. The ISO standard (ISO 17664) regulating what should be included in the instructions for use (IFU) was also updated with demands for validated cleaning, disinfection and sterilization processes for reusable devices. Also for achieving FDA approval, validation of applicable decontamination processes is a major factor.

We can help you to develop, optimize and validate your medical device processes and documentation for regulatory authorities.

RISE offers:

- Development and validation of cleaning processes
- Identification of contaminants
- Surface and residue analysis
- Bioburden analysis
- Validation of effectiveness of reprocessing methods
- Validation of compatibility of the products with the methods

Why RISE?

- Long experience of working with medtech industry and healthcare sector
- Access and compliance to standards within the field
- Not just a test lab - researchers and experts in material science, additive manufacturing, chemistry and biology

Contact details
Biology: Josefin Seth Caous
josefin.caous@ri.se, 010-526 59 96

Material science: Sarunas Petronis
sarunas.petronis@ri.se, 010-516 58 66

ID: 4311