ISO 14698 Compliance

BIOCONTAMINATION TESTING STRATEGY

LATEST INVESTMENT

In support of Plastikos' and Plastikos Medical's continued improvement and risk mitigation efforts, the companies recently implemented a formal system, in full compliance with ISO 14698-1 and ISO 14698-2. This system functions as a comprehensive test for bio-contamination, and evaluates microbiological data for Medical OEM customers who request this level of bio-contamination control in support of their life-saving and life-sustaining products.

Medical device components are currently molded within multiple ISO-7 certified cleanrooms at Plastikos and Plastikos Medical that meet ISO-13485 manufacturing standards. Additionally, the development of this bio-contamination testing strategy significantly increases the specific level of bioburden confidence afforded to Plastikos' & Plastikos Medical's medical device OEM customers.

- ISO 14698-1: Includes the general principles and methods of biocontamination control.
- ISO 14698-2: Covers the complete evaluation and interpretation of the biocontamination data.

By obtaining reliable bio-contamination data from multiple sampling locations throughout the cleanrooms, especially in 'risk zones', Plastikos' & Plastikos Medical's test results provide a comprehensive bacterial & fungal analysis and a heightened accuracy in relation to cultured results as well as the documentation of trending data over time.

This rigorous level of bioburden testing has traditionally been completed by the medical device OEM's throughout the assembly of a medical device to verify bio-contamination levels prior to the sterilization process. By providing the enhanced testing capability to identify any microbial activity in-house, Plastikos & Plastikos Medical can now quantifiably increase the confidence that its manufactured parts meet the medical customer's bioburden requirements, so they can move forward with their own downstream assembly, sterilization, and packaging processes. Ultimately, our ISO 14698 compliance yields a significantly increased level of risk mitigation to the Medical Device OEM, to the downstream supply chain, and to the finished medical device.

ENHANCED ENVIRONMENTAL CONTROL CAPABILITIES

- Increased efficiency and risk mitigation to the Medical Device OEM
- NEW capability to perform both Passive and Active Air Testing for microbials in an ISO 13485 certified, ISO-7 cleanroom environment
- Active & Passive Air Testing requirements meet 10 CFU (Colony Forming Units)
- Quarterly Comprehensive Bacterial and Fungal Analysis

EXECUTIVE RESPONSE

"Adding a level of bio-contamination control to our already proven and certified cleanroom capabilities affords our customers with a level of confidence that few other custom medical molders & medical manufacturers provide. Knowing that our products meet stringent bioburden limits directly increases our customers' ability to ensure that they are providing a safer finished product to all of their end consumers."

Joe Day, Quality Manager

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