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Cleanrooms and associated controlled environments —

Part 18: Assessment of suitability of consumables

Salles propres et environnements maîtrisés apparentés —
Partie 18: Évaluation de l'aptitude à l'emploi des consommables

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Foreword

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A list of all parts in the ISO 14644 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Cleanrooms and associated controlled environments are used for the control of contamination to levels appropriate for performing contamination-sensitive activities.

Products and processes that benefit from the control of contamination include those in industries such as aerospace, microelectronics, optics, displays, nuclear, micro-mechanical devices, consumer goods, cosmetics and life sciences (e.g. pharmaceuticals, medical devices, food). Contamination control in the healthcare sector benefits the patients by enabling access to products free of potentially harmful particles.

Consumables are widely used during preparation and operations in cleanrooms, clean zones or controlled zones to maintain the air or surface cleanliness level in the cleanroom by shielding a contamination source or a vulnerable object or by removing contamination from a surface. For monitoring and testing purposes, consumables can be used for sampling contamination. Consumables need to be carefully selected and appropriately used in order to maintain cleanliness levels and mitigate risk for processes and products.

Consumables are used for a limited time only. They do not constitute a part of the final product.

This document addresses the suitability assessment of consumables for use in cleanrooms, clean zones or controlled zones in respect to contamination in air and on surfaces by:

— particles;

— chemicals;

— microorganisms.

Customers or users need to have the opportunity to assess a given consumable by matching their intended use requirements with the designed use data of the supplier. This can be supplemented by additional tests. This match of intended use and designed use is addressed as appropriate use.

Depending on the use case, an impact assessment to determine the kind and acceptable quantity of contamination from consumables can be derived by benchmarking the requirements with respect to emission of contaminants.

This document is written for suppliers (manufacturers of consumables or distributors) and customers (as users of consumables) to assess the cleanroom suitability of consumables.

The cleanroom suitability assessment always has to be accompanied with a description of use, technical data as required by the nature of the consumable and test results. A sole statement such as “suitable for cleanroom of classification ISO 5” is not foreseen, due to the variety and complexity of use cases and the likelihood that a cleanroom suitability assessment would not rely on test data relating solely to airborne particle emissions.