

Classification examples

B.1 Healthcare products

For the manufacture of healthcare products, a frequently used correlation of typical manufacturing applications and cleanroom classification levels is given (see Table B.1). At the process core, the sterile product is filled through an aseptic assembly of components in a clean zone, controlled for particulate and microbiological contamination.

To access the process core, both the personnel and the process materials traverse several shells of increasing cleanliness (decreasing particulate concentrations). Personnel moving between various zones of different levels of cleanliness may change garments between zones, in accordance with the requirements of the zone that they are entering. Materials that enter each zone should be treated in a method appropriate to the level to be entered to remove particulate and/or microbiological contamination.

Table B.1 — Cleanroom examples for aseptic processing of healthcare products

Air cleanliness class (ISO Class) in operation ^a	Airflow type ^b	Average, airflow velocity ^c m/s	Examples of applications
5 (at $\geq 0,5 \mu\text{m}$)	U	> 0,2	Aseptic processing ^d
7 (at $\geq 0,5 \mu\text{m}$)	N or M	na	Other processing zones directly supporting aseptic processing
B (at $\geq 0,5 \mu\text{m}$)	N or M	na	Support zones of aseptic processing, including controlled preparation zones

NOTE 1 Application-specific classification requirements should take into account other relevant regulations.

NOTE 2 na = not applicable

^a Occupancy states associated with the ISO Class should be defined and agreed in advance of establishing optimum design conditions.

^b When airflow type is listed, it represents the airflow characteristics for cleanrooms of that class: U = unidirectional; N = non-unidirectional; M = mixed (combination of U and N).

^c Average airflow velocity is the way that unidirectional airflow in cleanrooms is usually specified. The requirement on unidirectional airflow velocity will depend on specific application factors such as temperature, and configuration of the controlled space and the items to be protected. Displacement airflow velocity should be typically above 0,2 m/s.

^d Where operator protection is required to ensure safe handling of hazardous materials, the use of segregation concepts (see examples in annex A) or appropriate safety cabinets and devices should be considered.

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