During an inspection of your firm (I) (WE) observed:

Observation 1
Disinfecting agents and wipes used in the ISO 5 zone are not sterile.

Specifically,
A. The wipes used with the (b) (4) to sanitize the "(b) (4)" are not sterile.

B. The (b) (4) disinfectant used inside of the "(b) (4)" is not sterile.

Observation 2
Personnel engaged in aseptic processing were observed wearing non-sterile gloves.

Specifically,

The (b) (4) assembly within the (b) (4) are not identified as sterile, and there is no sporicidal treatment of the (b) (4) prior to sterile drug production in the (b) (4).

Observation 3
Pressure differentials between areas with different air classifications were not monitored prior or during sterile drug production.

Specifically,
On 5/9/2017, we observed sterile drug production pharmacist clean the "(b) (4)", located in an unclassified drug production room, with (b) (4) then replace the refuse bag located inside the ISO 5 zone. This exchange of the bags exposed the ISO 5 zone to the unclassified air. No air pressure monitoring is conducted to assure unclassified air did not ingress into the ISO 5 zone.
Observation 4
The ISO 5 classified area is located within a non-classified room.

Specifically, the "(b) (4)" used for aseptic filling of sterile products is located in an unclassified room.

Observation 5
Sinks or drains are present in the cleanroom where the ISO 5 zone is located.

Specifically, there is a sink and dishwasher located in the unclassified room where the "(b) (4)" is located.