

Latest CDSCO updated Post approval correction categories - 11.08.2025

PAC Major Categories

1. Change in respect of material of construction
2. Change of address of the overseas legal manufacturer (without change in the constitution)
3. Change of address of the overseas actual manufacturer (without change in the location and constitution)
4. Change in respect of model number of the devices
5. Change in respect of Accessories/components of the devices
6. Change in respect of Primary packaging material
7. Change in the method of sterilization
8. Change in respect of additional Brand Name
9. Change of the approved Shelf Life
10. Change in the Intended use or indication for use
11. Change in respect of design which shall affect quality in respect of its specifications, indication for use, performance and stability of the medical device
12. Change in respect of Label excluding change in font size, font type, color, label design
13. Change in respect of the Instructions for Use or User manual or Package insert
14. Change in respect of the manufacturing process, equipment or testing which shall affect quality of the device
15. Change of name of the overseas manufacturer or its manufacturing site (without change in the constitution)
16. Change of Address of the authorized agent (without change in the constitution)
17. Change of name of the authorized agent (without change in the constitution)

PAC Minor Categories

1. Change in respect of design which shall not affect quality in respect of its specifications, indication for use, performance and stability of the medical device
2. Change in respect of the manufacturing process, equipment, or testing which shall not affect quality of the device
3. Change in respect of the packaging specifications excluding primary packaging material
4. Amendment/Correction/Others