MD-14 Checklist for - Class A Products

1. Plant registration certificate
2. Free Sale Certificate
3. Quality Management System certificate or Full Quality Assurance certificate or Production Quality Assurance certificate i
4. Latest inspection or audit report
5. Device description, intended use of the device, specification including variants and accessories;
6. Material of construction
7. Working principle and use of a novel technology (if any);
8. Labels, package inserts (IFU, etc.,), user manual, wherever applicable,
9. Summary of any reported Serious Adverse Event in India or in any of the countries where device is marketed
10. Site or plant master file as specified in Appendix I of this Schedule;
11. Essential principles checklist for demonstrating conformity to the essential principles of safety and performance of the medical device;
12. Undertaking signed by the manufacturer stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule;
13. Wholesale license
14. Constitutional details
15. POA
16. Legal Form MD-14