Documents Required for registration of Medical Device from the Directorate General of Drug Administration, Bangladesh:

1. Agency agreement or nomination of local agent
2. Details Company Profile
3. Complete Product Dossier including:
   a)Manufacturing Procedure, b)QC & QA procedure with the name of technical personnel, c)Sterilization procedure, d)clinical trial documents, e)product recall procedure, f)plant lay with floor plan etc documents.
4. Attested copies of CPP/FSC of Country of Origin attested by Bangladeshi Embassy
5. English and Bengali version of the printed packaging materials and Dossier.
6. Test protocol and analytical certificate.
7. Complete packaging materials of the devices mentioning manufacturers name & address, batch/lot no., specification & size, Manufacturing date, expiry date, Sterility status.
8. Required blister packing/ribon packing for disposable syringe.
9. Complete Annexure 3 form (to be completed after getting the above mentioned documents).
10. EC Certificate
11. Declaration of Conformity/Conformity assessment