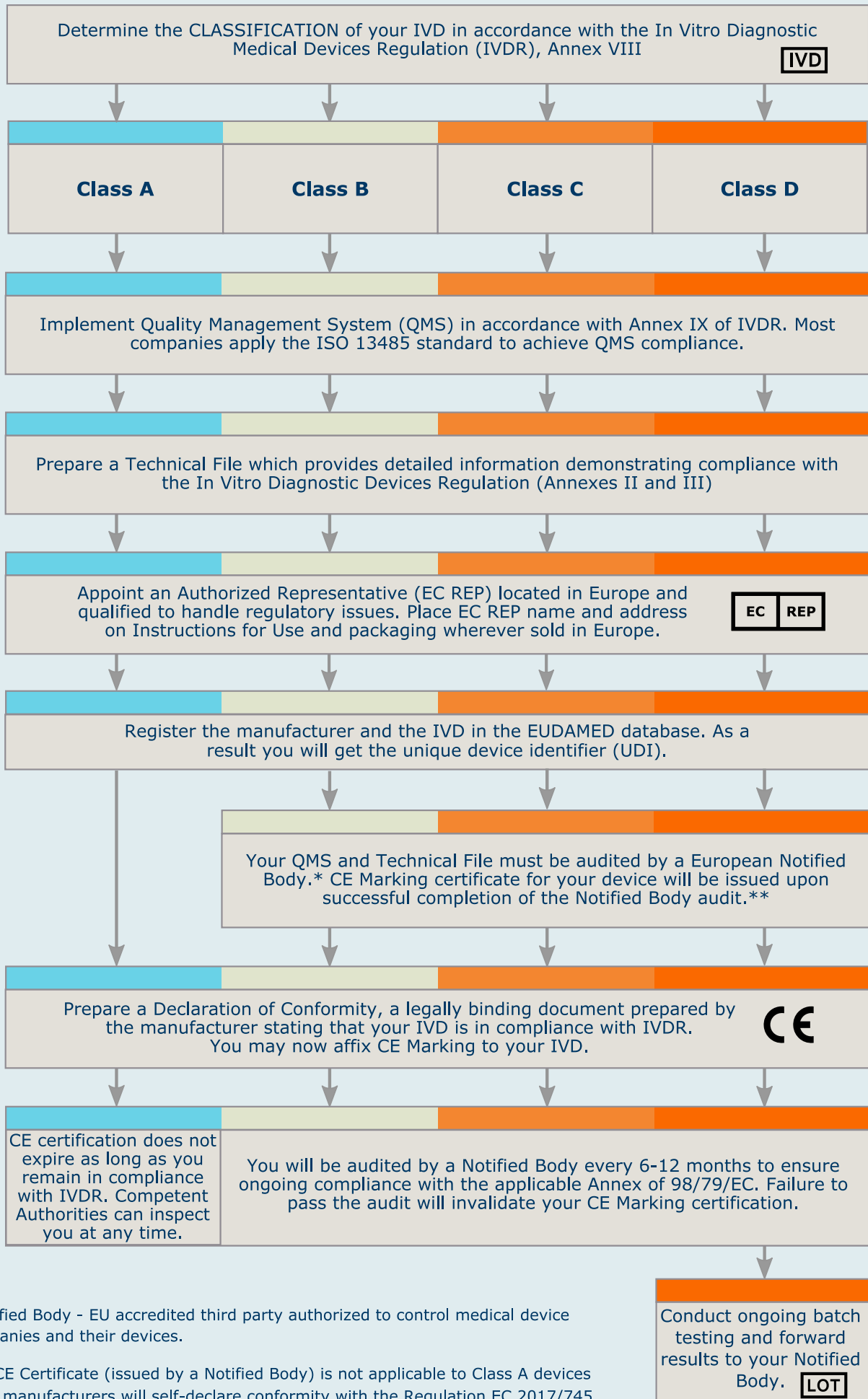




EUROPEAN UNION: REGULATORY APPROVAL PROCESS FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES



*Notified Body - EU accredited third party authorized to control medical device companies and their devices.

**A CE Certificate (issued by a Notified Body) is not applicable to Class A devices since manufacturers will self-declare conformity with the Regulation EC 2017/745.