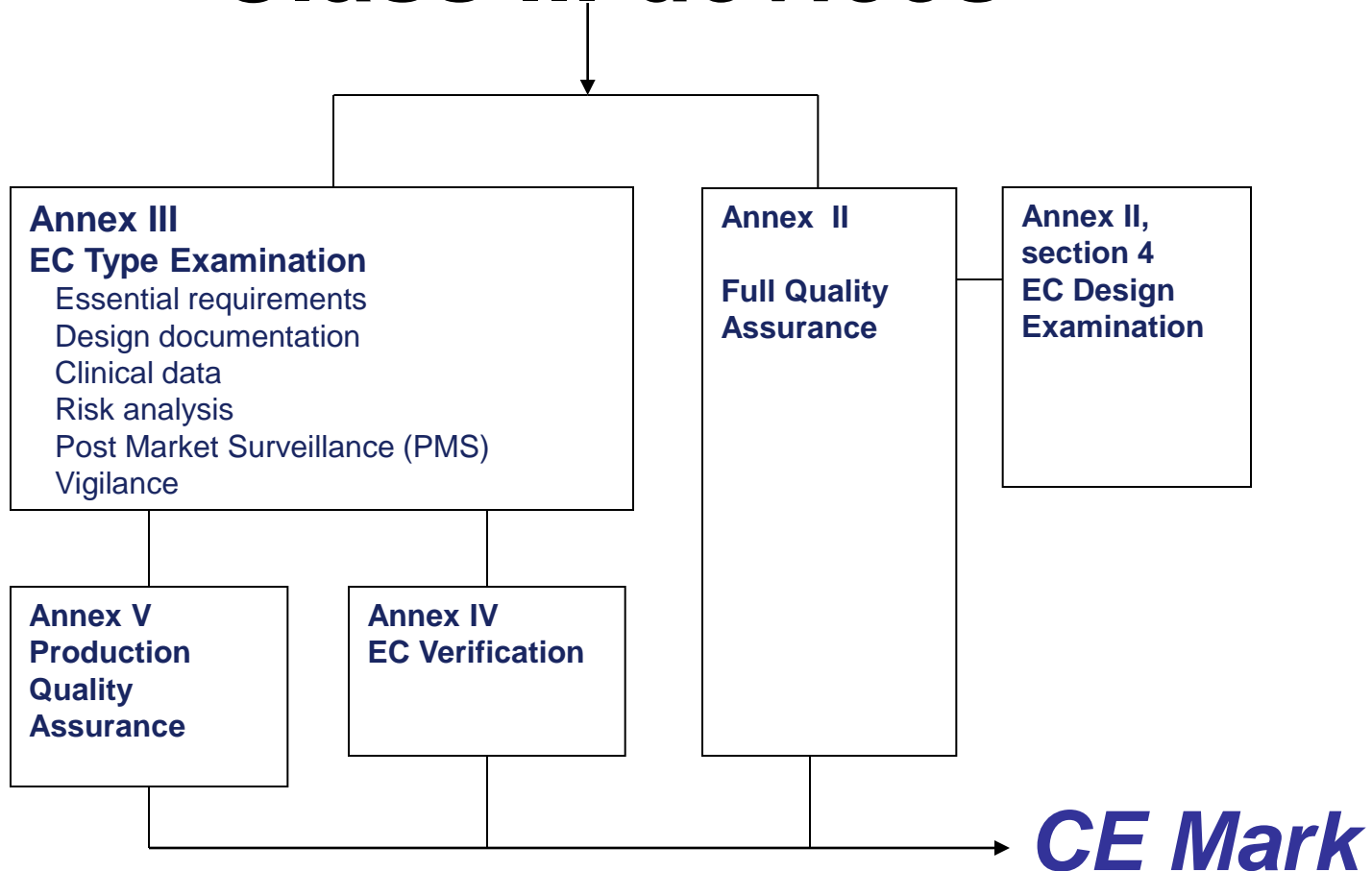


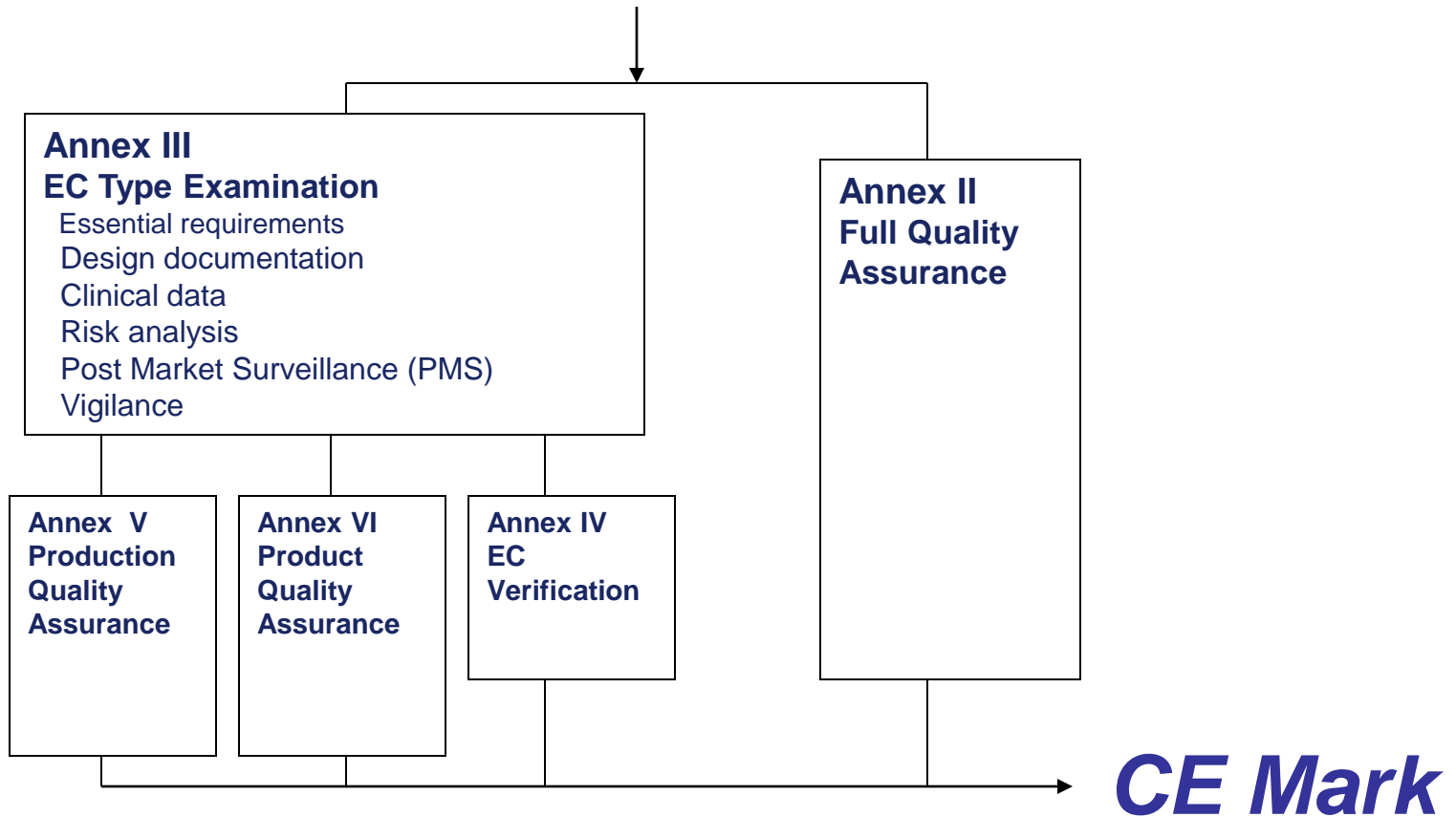
Routes to the CE Mark



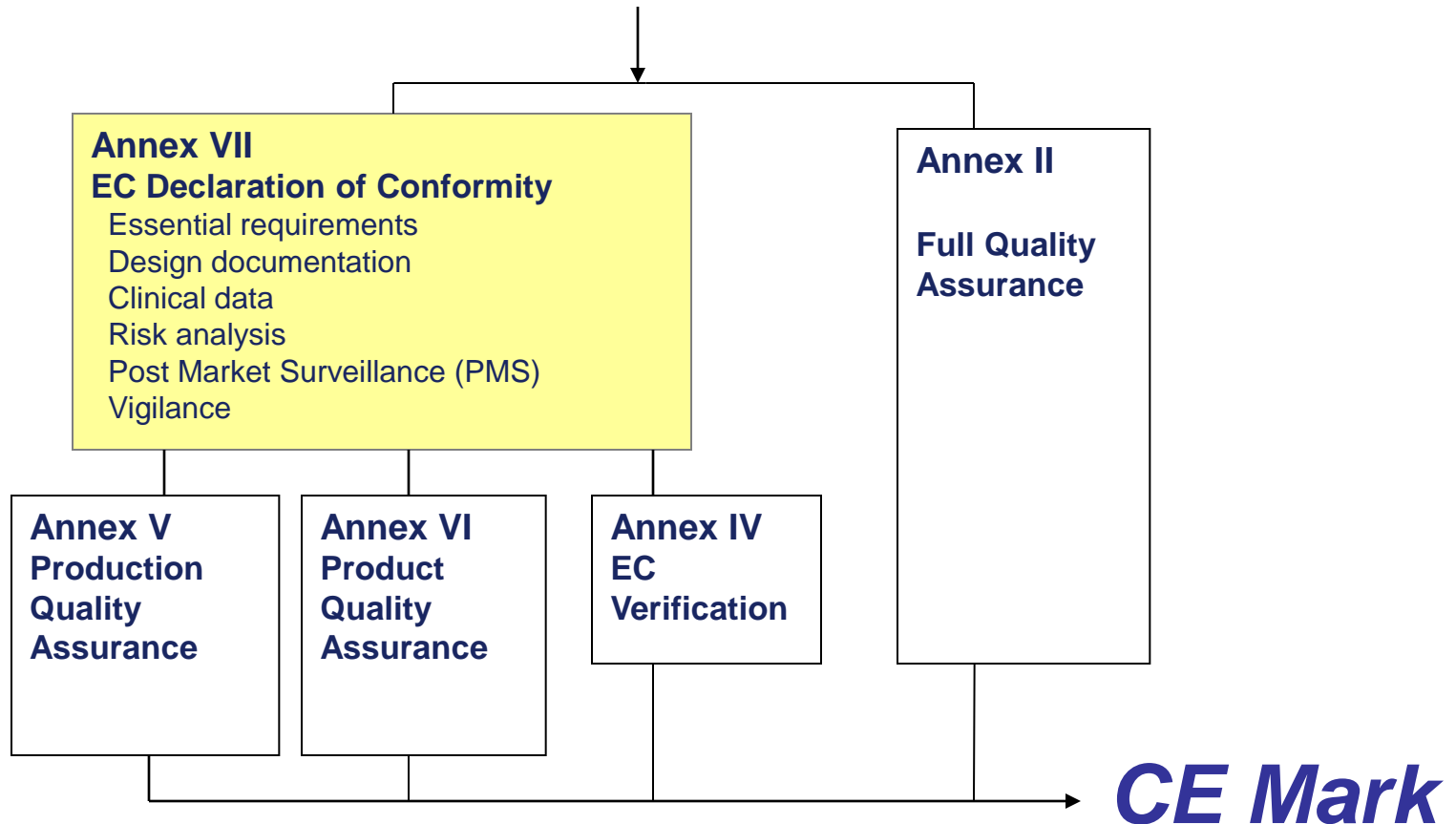
Class III devices



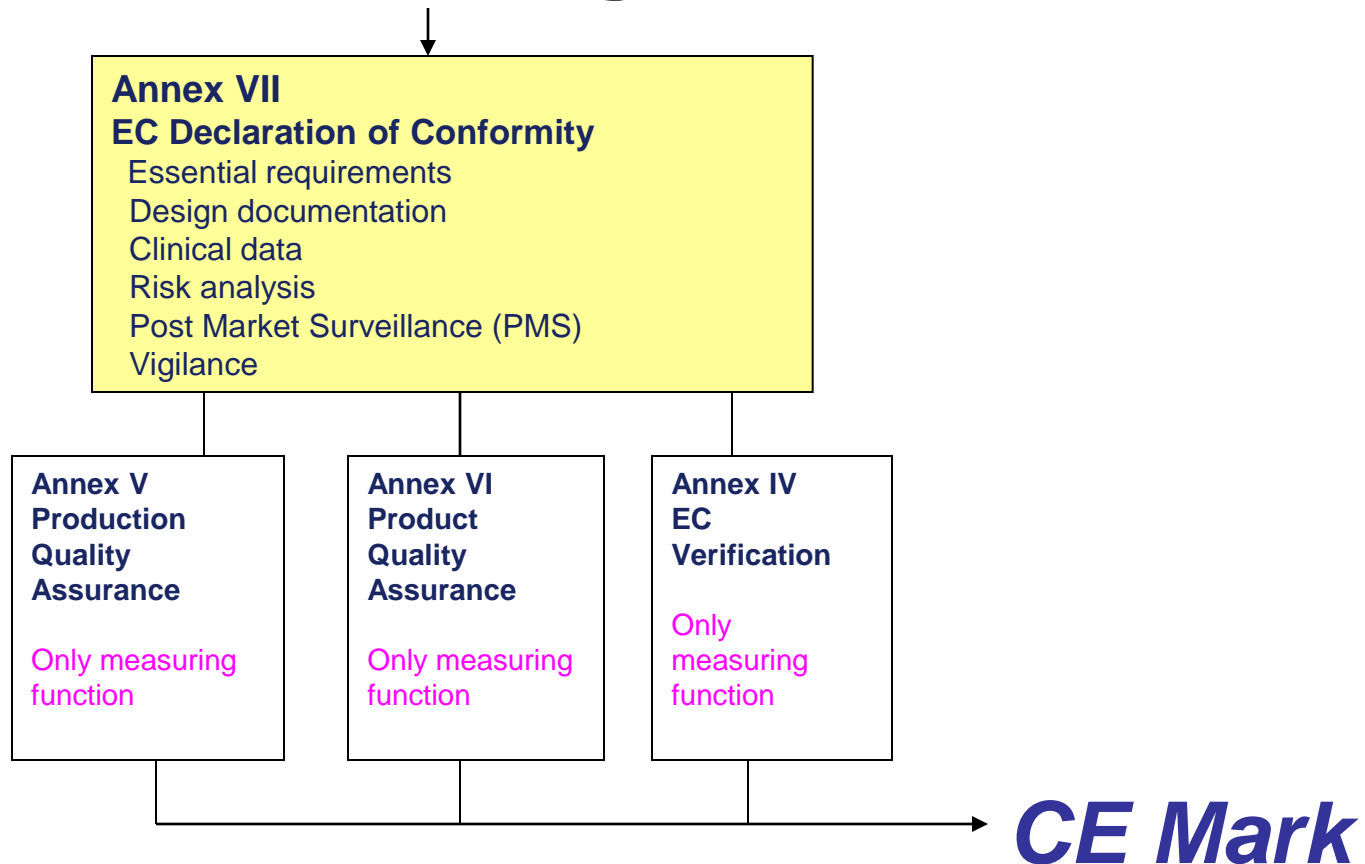
Class IIb devices



Class IIa devices



Class I devices with a measuring function



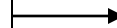
Class I devices, sterile



Annex VII
EC Declaration of Conformity
Essential requirements
Design documentation
Clinical data
Risk analysis
Post Market Surveillance (PMS)
Vigilance

Annex V
Production Quality Assurance

Only sterilization



CE Mark



Class I devices



CE Mark

