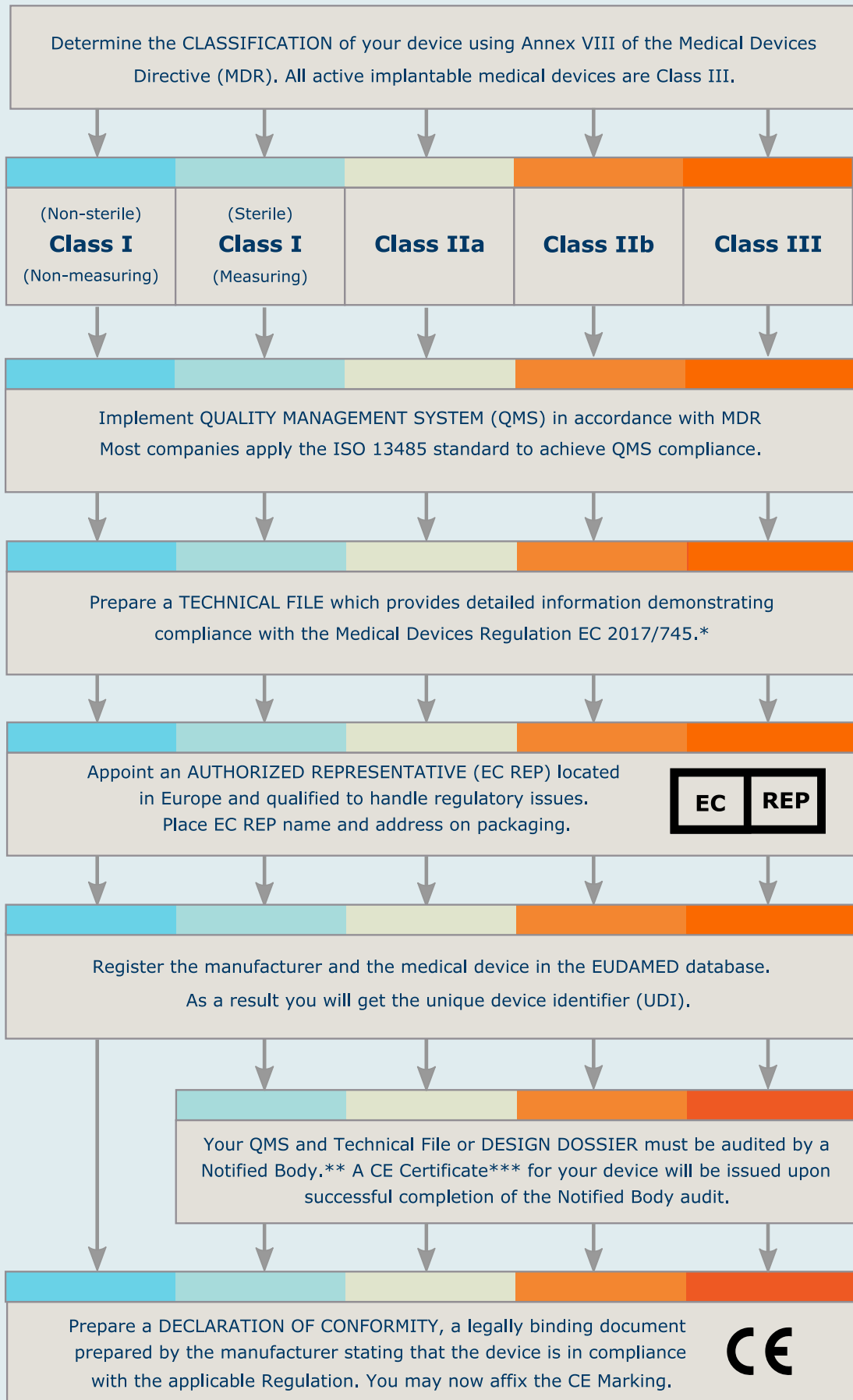




# EUROPEAN UNION: REGULATORY APPROVAL PROCESS FOR MEDICAL DEVICES



\*Class III devices as well as active implantable devices will likely require substantial clinical trial data. Clinical trials conducted in Europe must be pre-approved by a Competent Authority. Existing clinical data may be acceptable. All data are reviewed and approved by a Notified Body.

\*\*Notified Body = EU accredited third party authorized to conduct audits of medical device companies and their devices.

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