

Medical Device Directive 93/42/EEC "Route to Compliance"

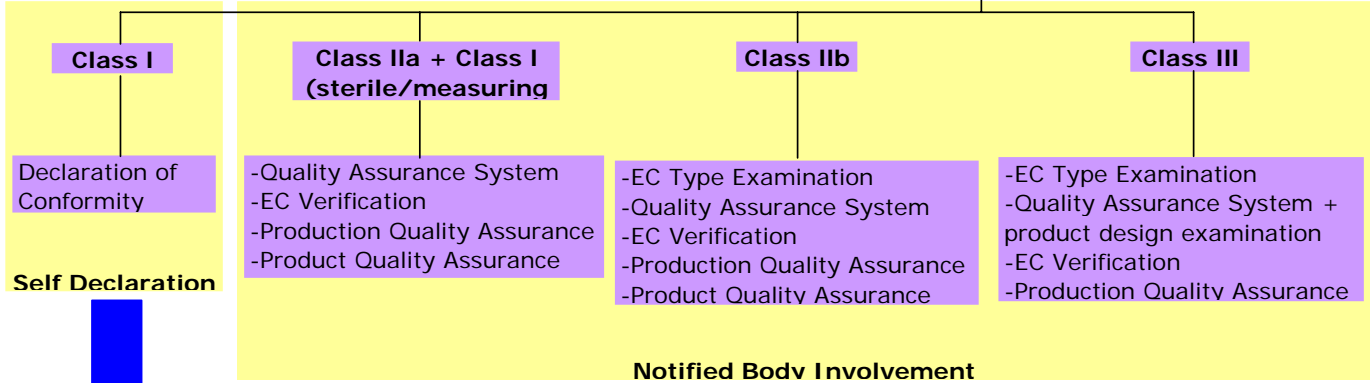
Within the scope of :
 Medical Device Directive 93/42/EEC
 In-vitro Diagnostic Device Directive 98/79/EC
 Active Implantable Medical Device Directive 90/358/EEC

Is device: Rules determine classification

Non- invasive Transient Rules 1-4
 Invasive Short term Rules 5-8
 Active Long term Rules 9-12
 Special Rules 13-18

1. Determine Classification

2. Conformity Assesment Route



3. Compile Technical File



4. Authorized Representative required?

Labeling & instructions for use
 Device registration
 Vigilance & Post Market Surveillance

5. DECLARATION OF CONFORMITY

