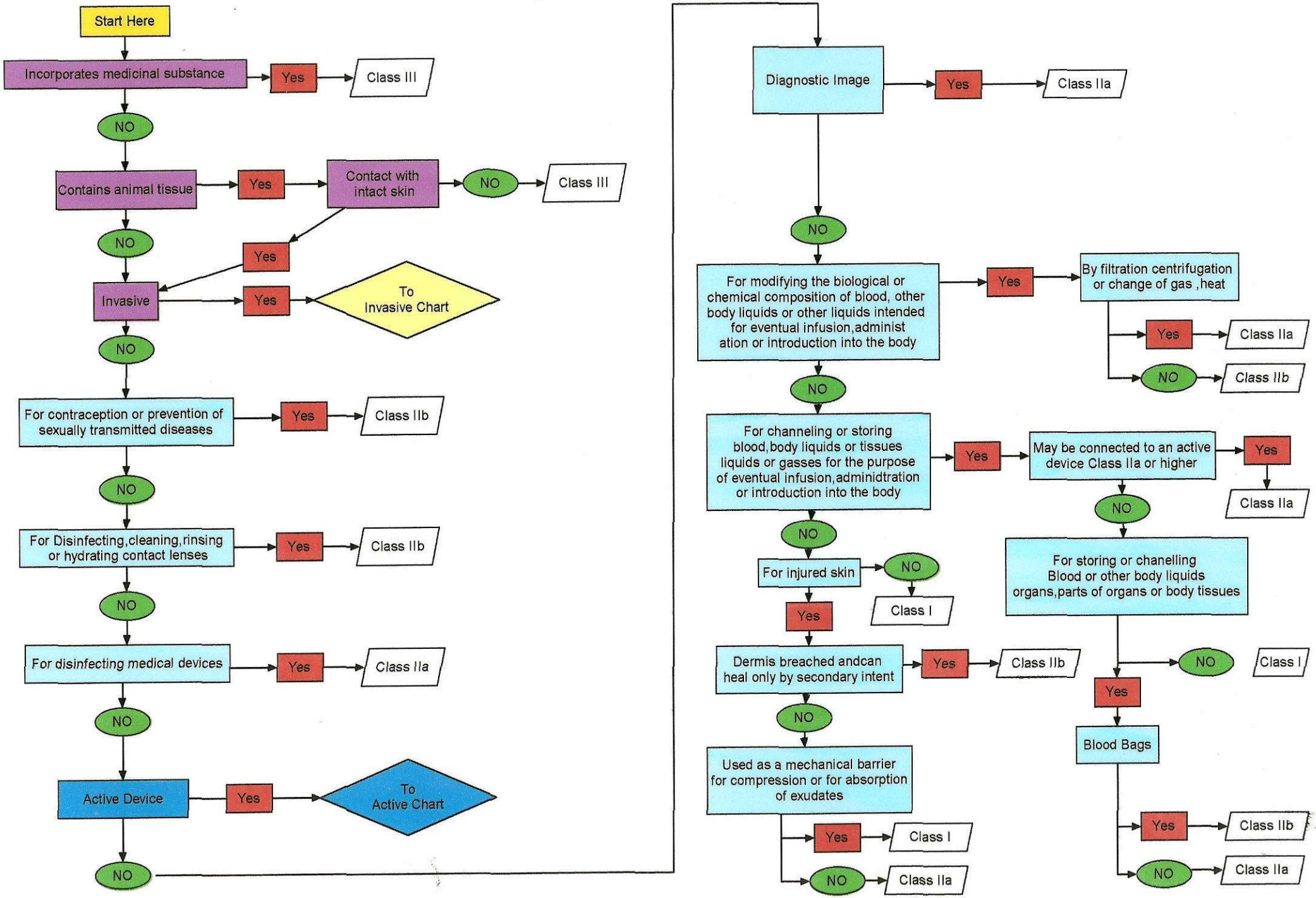
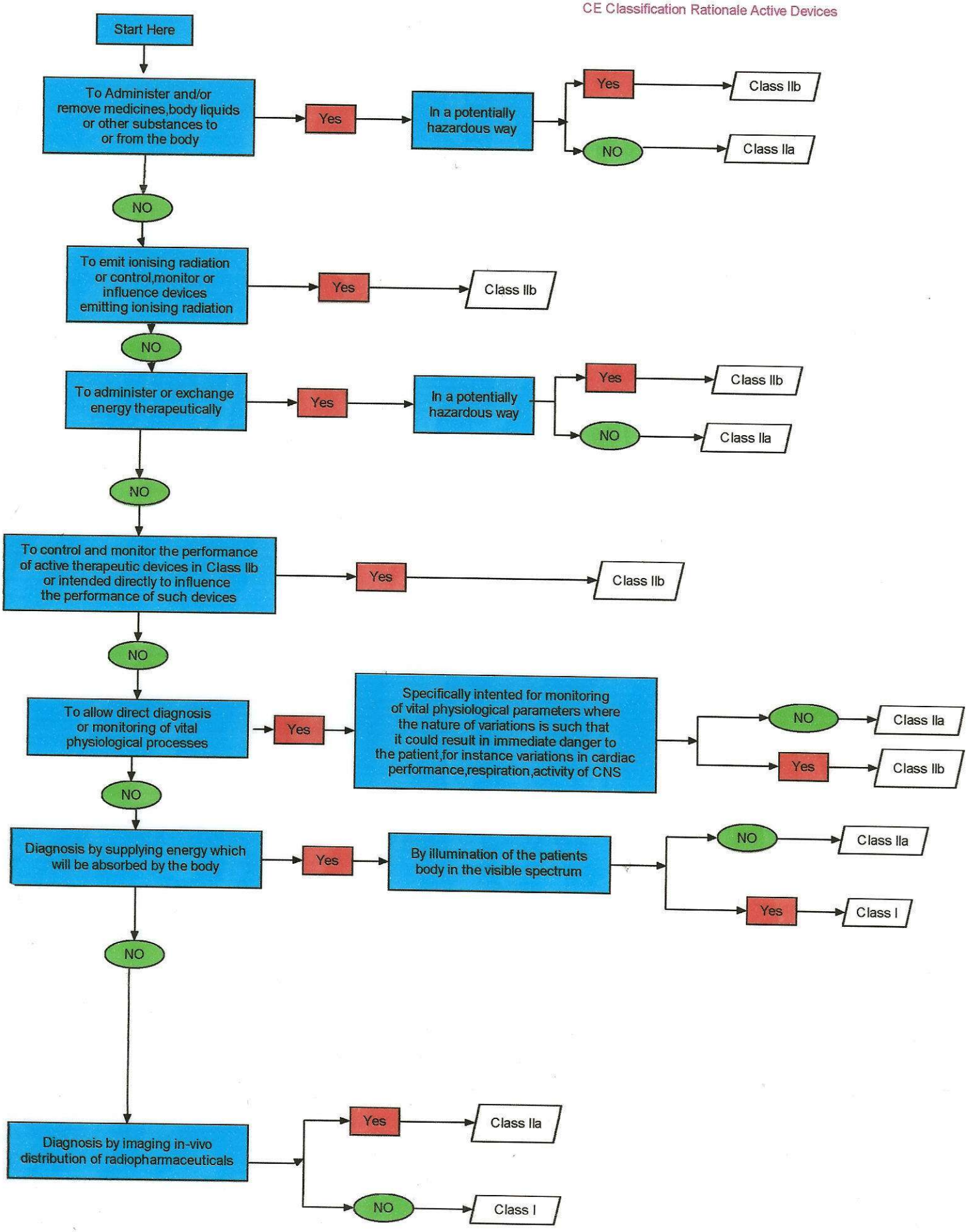
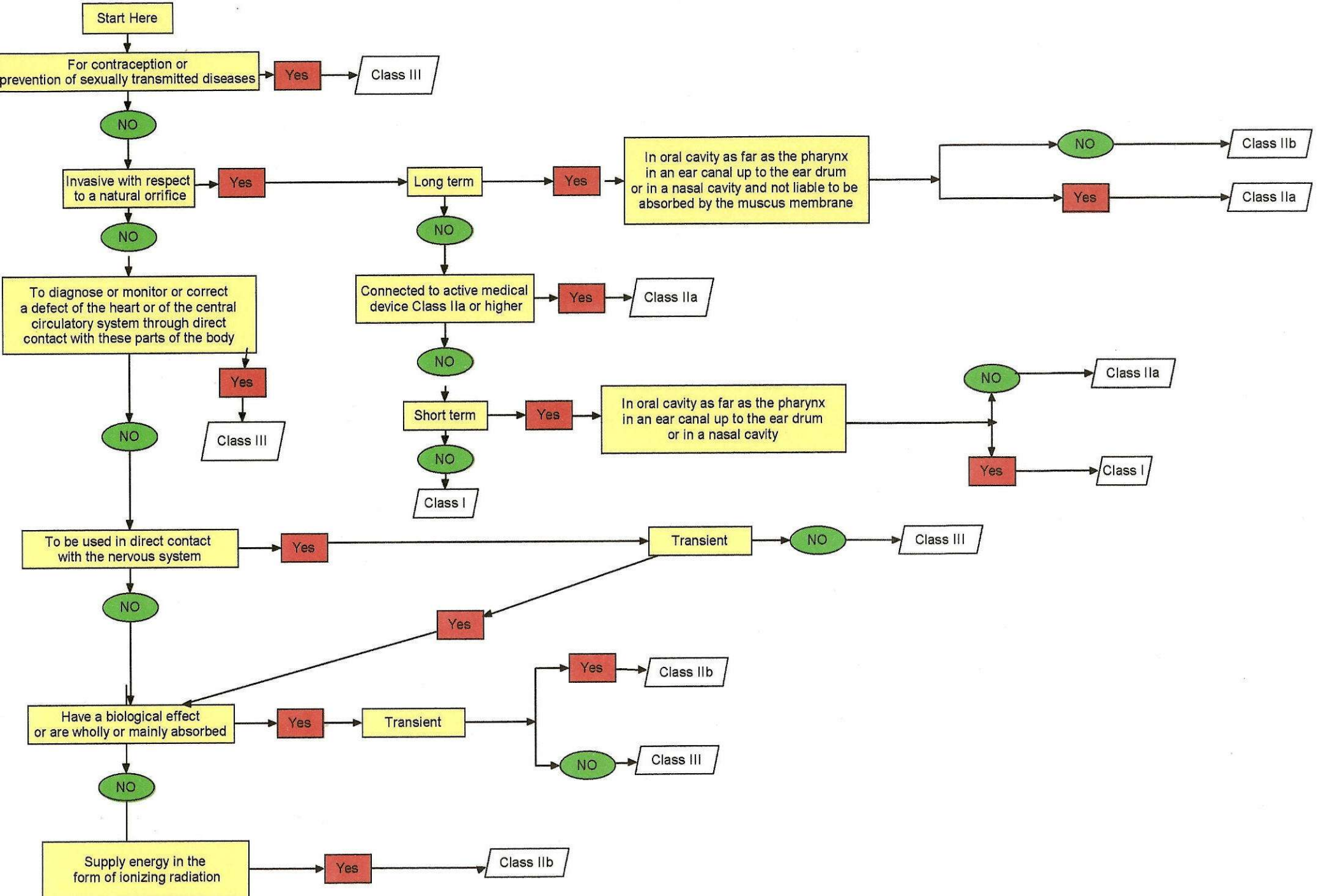
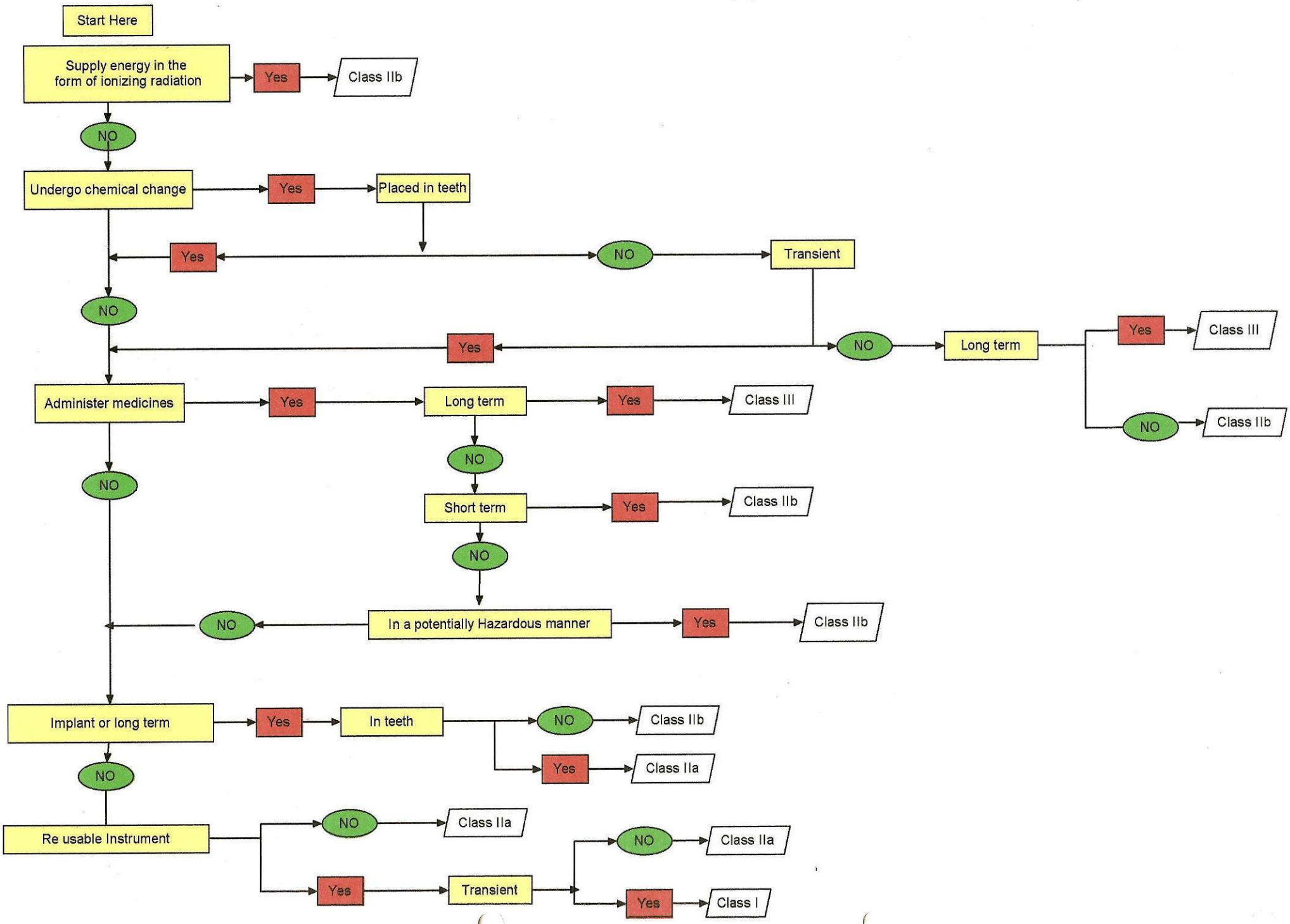
CE Classification Rationale




Start Here
To Administer and/or remove medicines,body liquids or other substances to or from the body
Yes
In a potentially hazardous way
Yes
Class IIb
NO
Class IIa
NO
To emit ionising radiation or control,monitor or influence devices emitting ionising radiation
Yes
Class IIb
NO
To administer or exchange energy therapeutically
Yes
In a potentially hazardous way
Yes
Class IIb
NO
Class IIa
NO
To control and monitor the performance of active therapeutic devices in Class IIb or intended directly to influence the performance of such devices
Yes
Class IIb
NO
To allow direct diagnosis or monitoring of vital physiological processes
Yes
Specifically intented for monitoring of vital physiological parameters where the nature of variations is such that it could result in immediate danger to the patient,for instance variations in cardiac performance,respiration,activity of CNS
NO
Class IIa
Yes
Class IIb
NO
Diagnosis by supplying energy which will be absorbed by the body
Yes
By illumination of the patients body in the visible spectrum
NO
Class IIa
Yes
Class I
NO
Diagnosis by imaging in-vivo distribution of radiopharmaceuticals
Yes
Class IIa
NO
Class I

CE Classification Rationale Invasive




Start Here
Supply energy in the form of ionizing radiation
Yes
Class IIb
NO
Undergo chemical change
Yes
Placed in teeth
Yes
NO
Transient
NO
Yes
NO
Long term
Yes
Class III
NO
Class IIb
Administer medicines
Yes
Long term
Yes
Class III
NO
Short term
Yes
Class IIb
NO
NO
In a potentially Hazardous manner
Yes
Class IIb
NO
Implant or long term
Yes
In teeth
NO
Class IIb
Yes
Class IIa
NO
Re usable Instrument
NO
Class IIa
Yes
Transient
NO
Class IIa
Yes
Class I