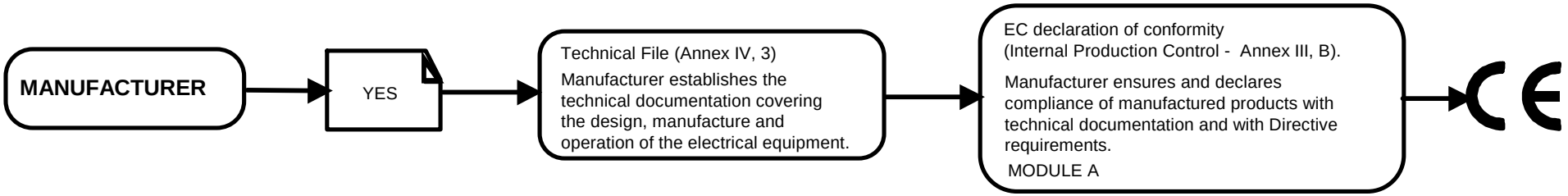
Flowchart presentation of conformity assessment procedures as provided for by the directives

New Approach Directives

1. Low voltage equipment (73/23/EEC, amendment 93/68/EEC)
2. Simple pressure vessels (87/404/EEC, amendments 90/488/EEC and 93/68/EEC)
3. Toys (88/378/EEC, amendment 93/68/EEC)
4. Electromagnetic compatibility (89/336/EEC, amendments 92/31/EEC and 93/68/EEC)
5. Machinery (98/37/EC, amendment 98/79/EC)
6. Personal protective equipment (89/686/EEC, amendments 93/68/EEC, 93/95/EEC and 96/58/EC)
7. Non-automatic weighing instruments (90/384/EEC, amendment 93/68/EEC)
8. Active implantable medical devices (90/385/EEC, amendments 93/42/EEC and 93/68/EEC)
9. Gas appliances (90/396/EEC, amendment 93/68/EEC)
10. Hot water boilers (92/42/EEC, amendment 93/68/EEC)
11. Civil explosives (93/15/EEC)
12. Medical devices (93/42/EEC, amendment 98/79/EC)
13. Potentially explosive atmospheres (94/9/EC)
14. Recreational craft (94/25/EC)
15. Lifts (95/16/EC)
16. Refrigeration appliances (96/57/EC)
17. Pressure equipment (97/23/EC)
18. Telecommunications terminal equipment (98/13/EC)
19. In vitro diagnostic medical devices (98/79/EC)
20. Radio and telecommunications terminal equipment (99/5/EC)

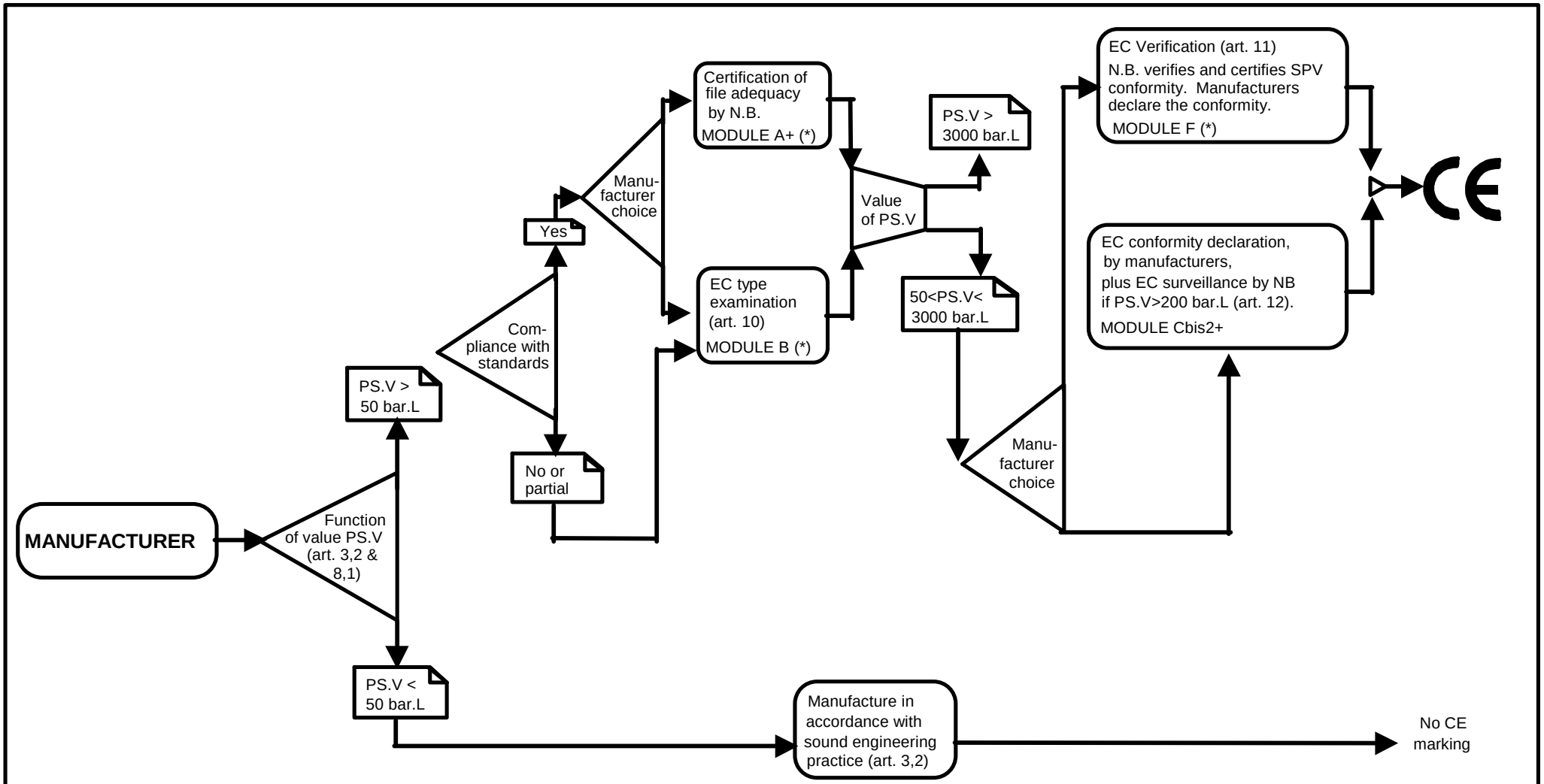
Directive based on the principles of the Global Approach, but which does not provide for the CE marking

21. Marine equipment (96/98EC)



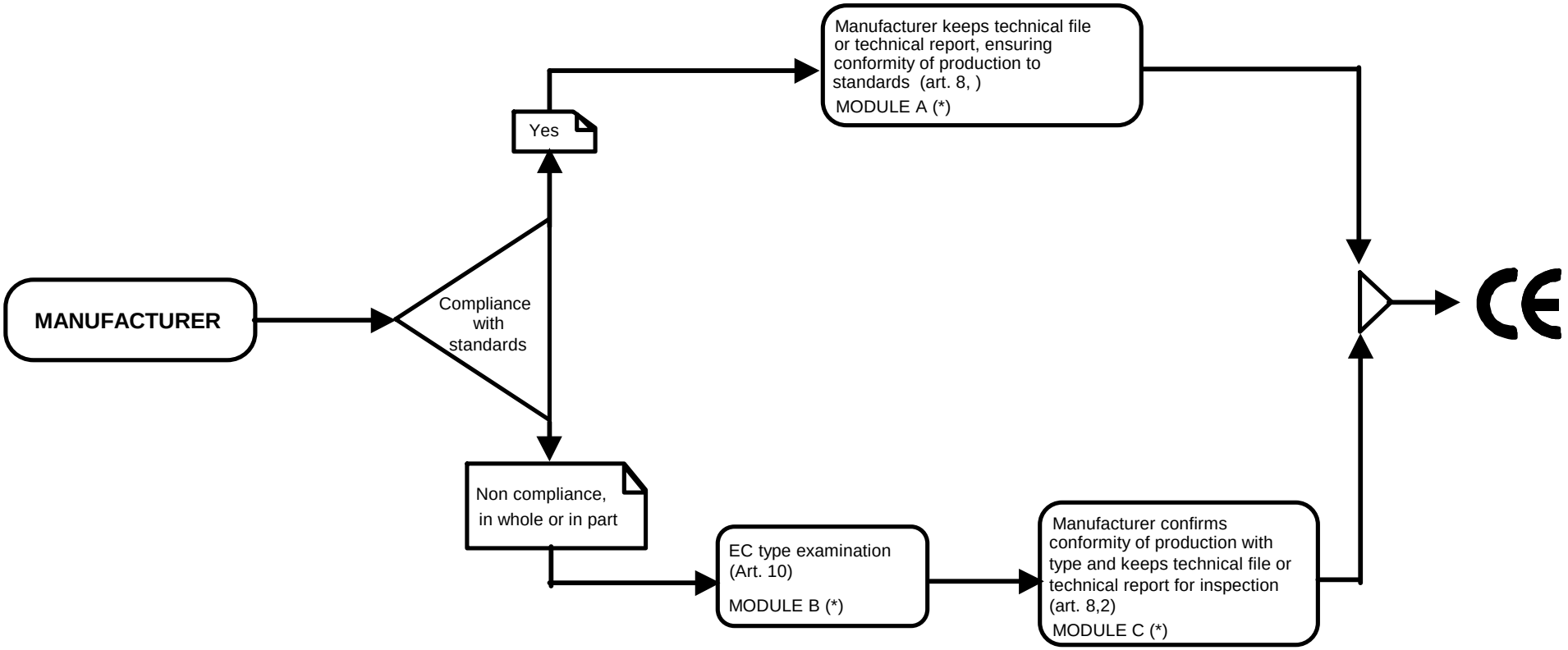
Flowchart for the conformity assessment procedures provided for in Directive 73/23/EEC on electrical equipment designed for use within certain voltage limits

Note: in the event of a challenge the manufacturer may submit a “report by a notified body” on the conformity of the equipment with the safety objectives (art. 8,2).



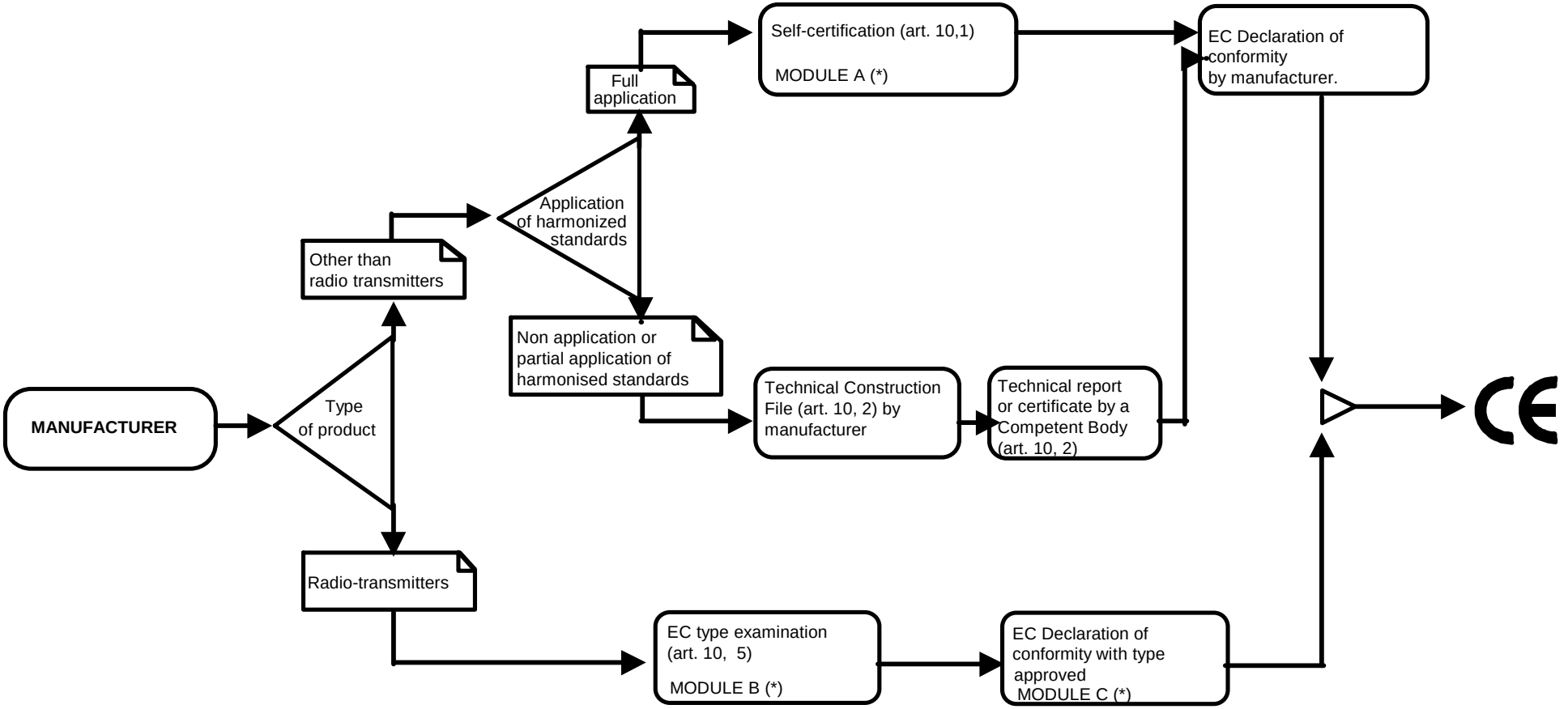
Flowchart for the conformity assessment procedures provided for in the Directive 87/404/EEC on simple pressure vessels

(*) These procedures were approved before the adoption of the Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.



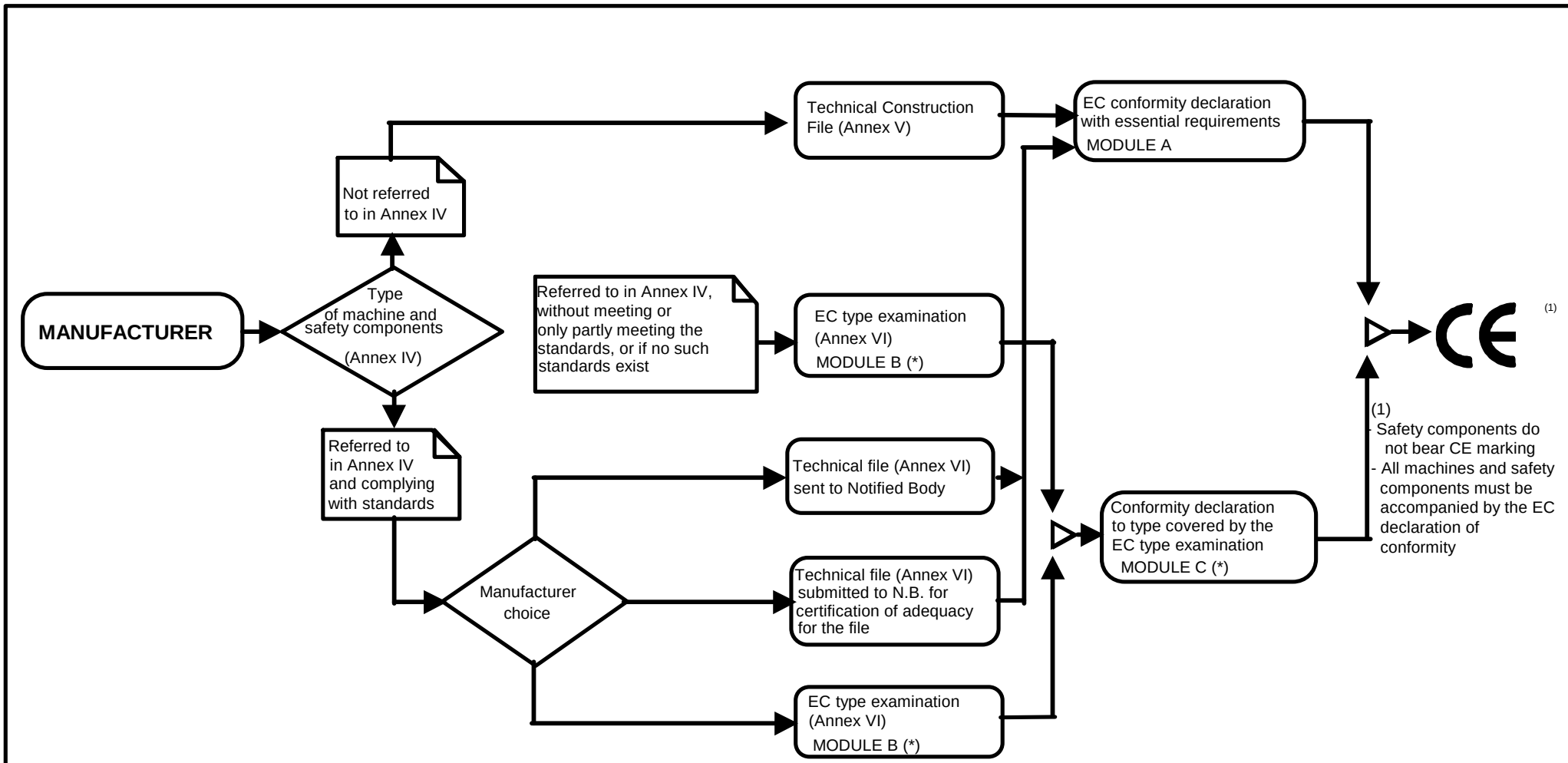
Flowchart for the conformity assessment procedures provided for in the Directive 88/378/EEC on safety of toys

(*) These procedures were approved before the adoption of the Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.



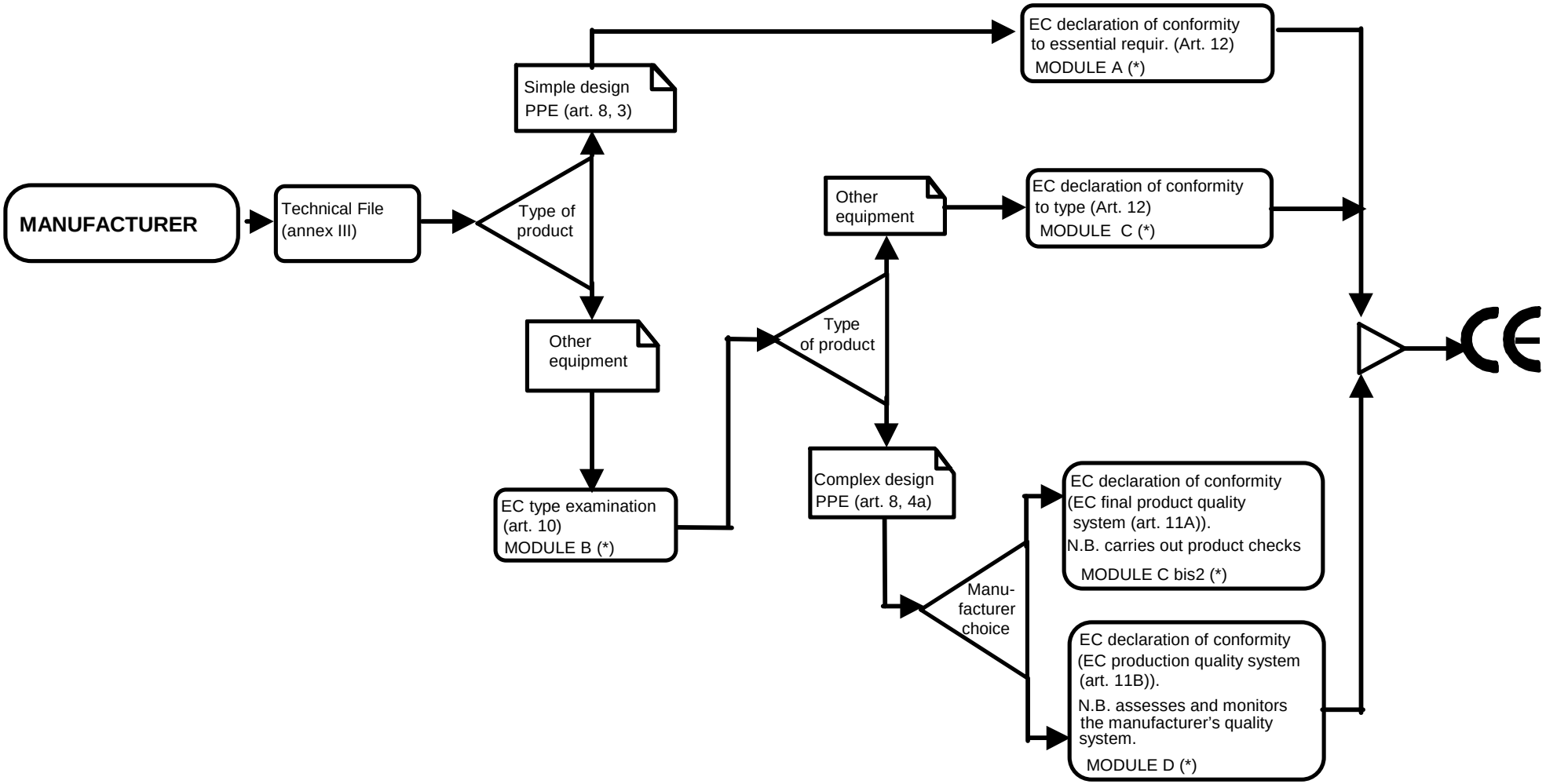
Flowchart for the conformity assessment procedures provided for in the Directive 89/336/EEC on electromagnetic compatibility

(*) These procedures were approved before the adoption of the Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.



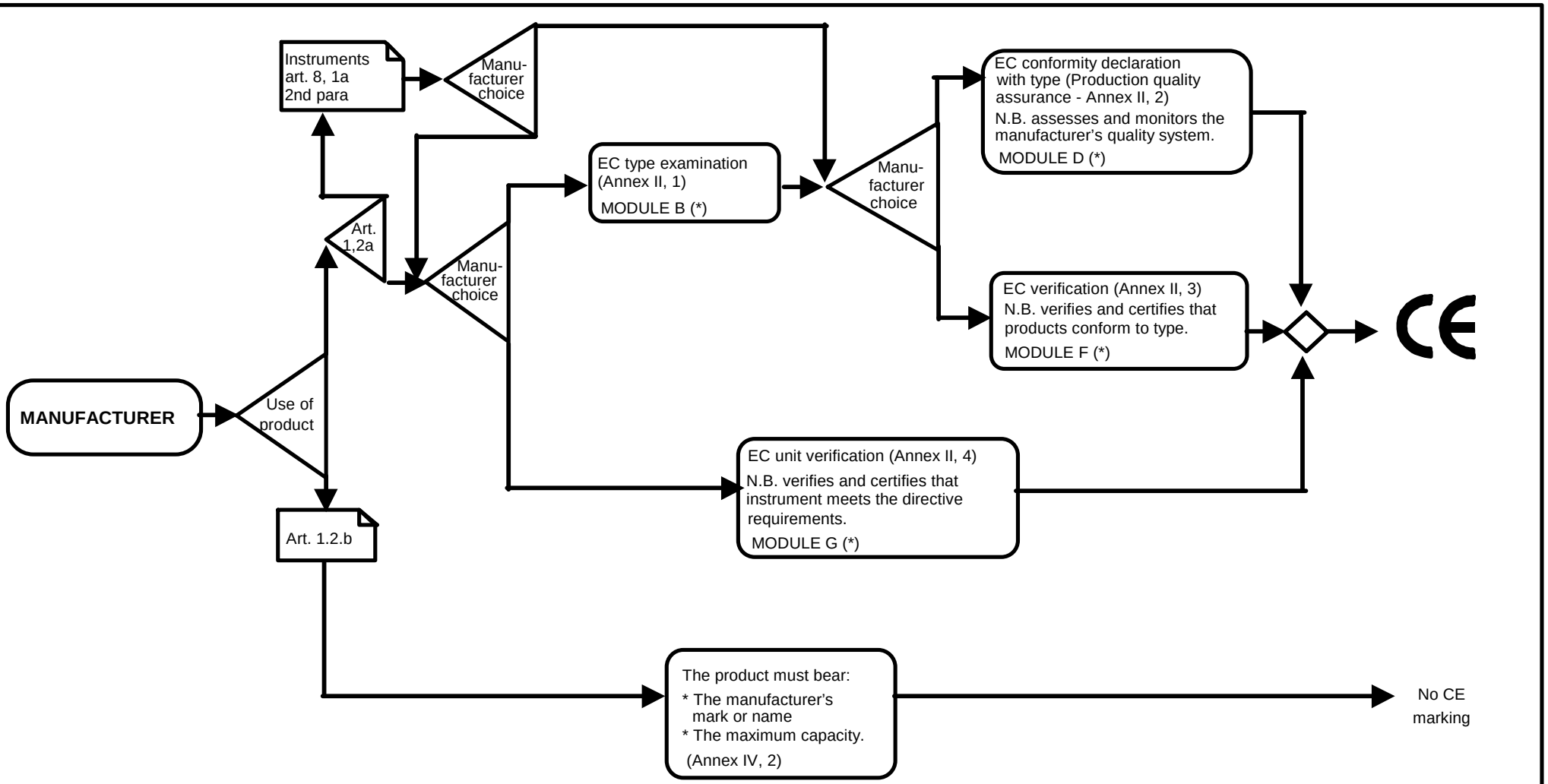
Flowchart for the conformity assessment procedures provided for in the Directive 98/37/EC on machinery

(*) These procedures were approved before the adoption of the Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.



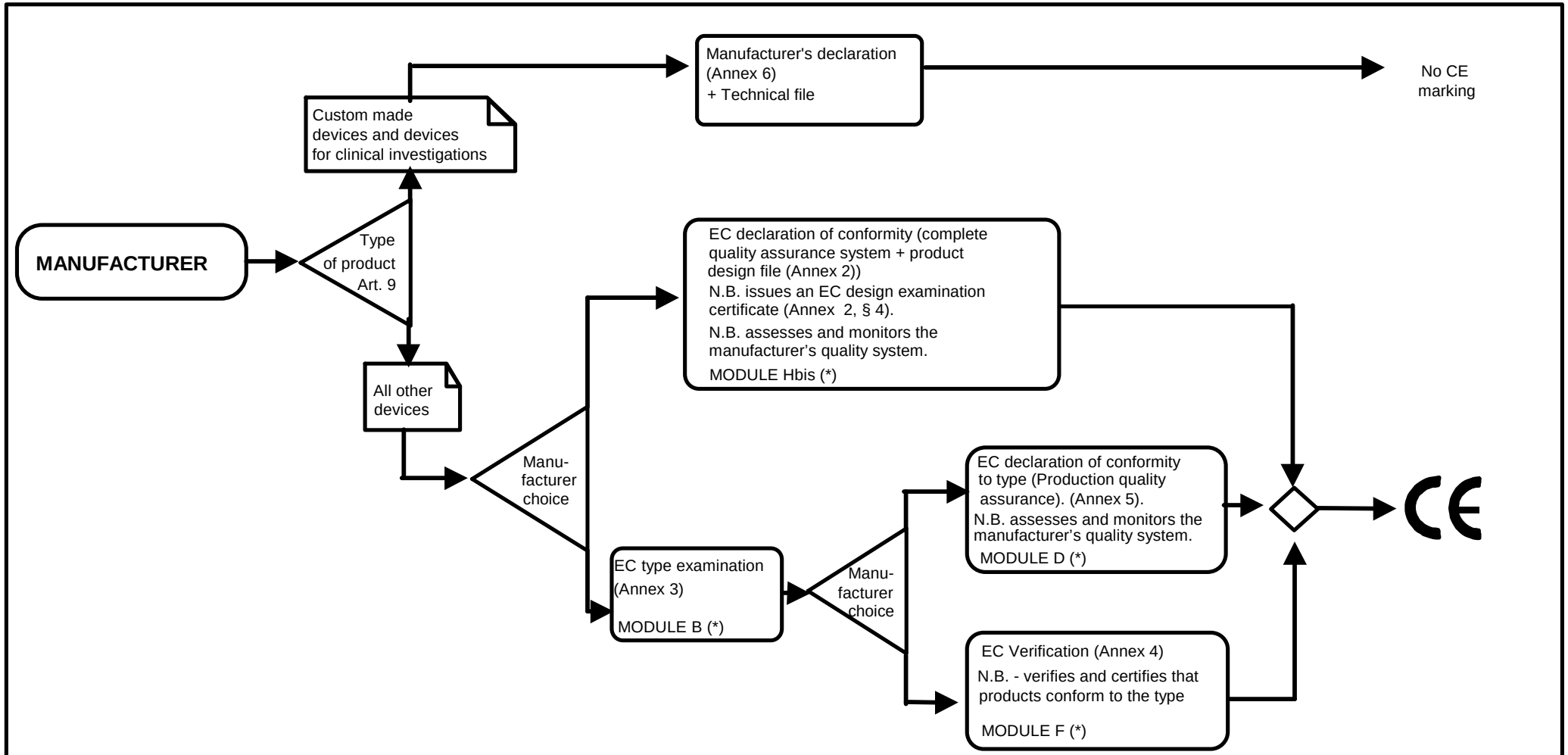
Flowchart for the conformity assessment procedures provided for in the Directive 89/686/EEC on personal protection equipment (PPE)

(*) These procedures were approved before the adoption of the Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.



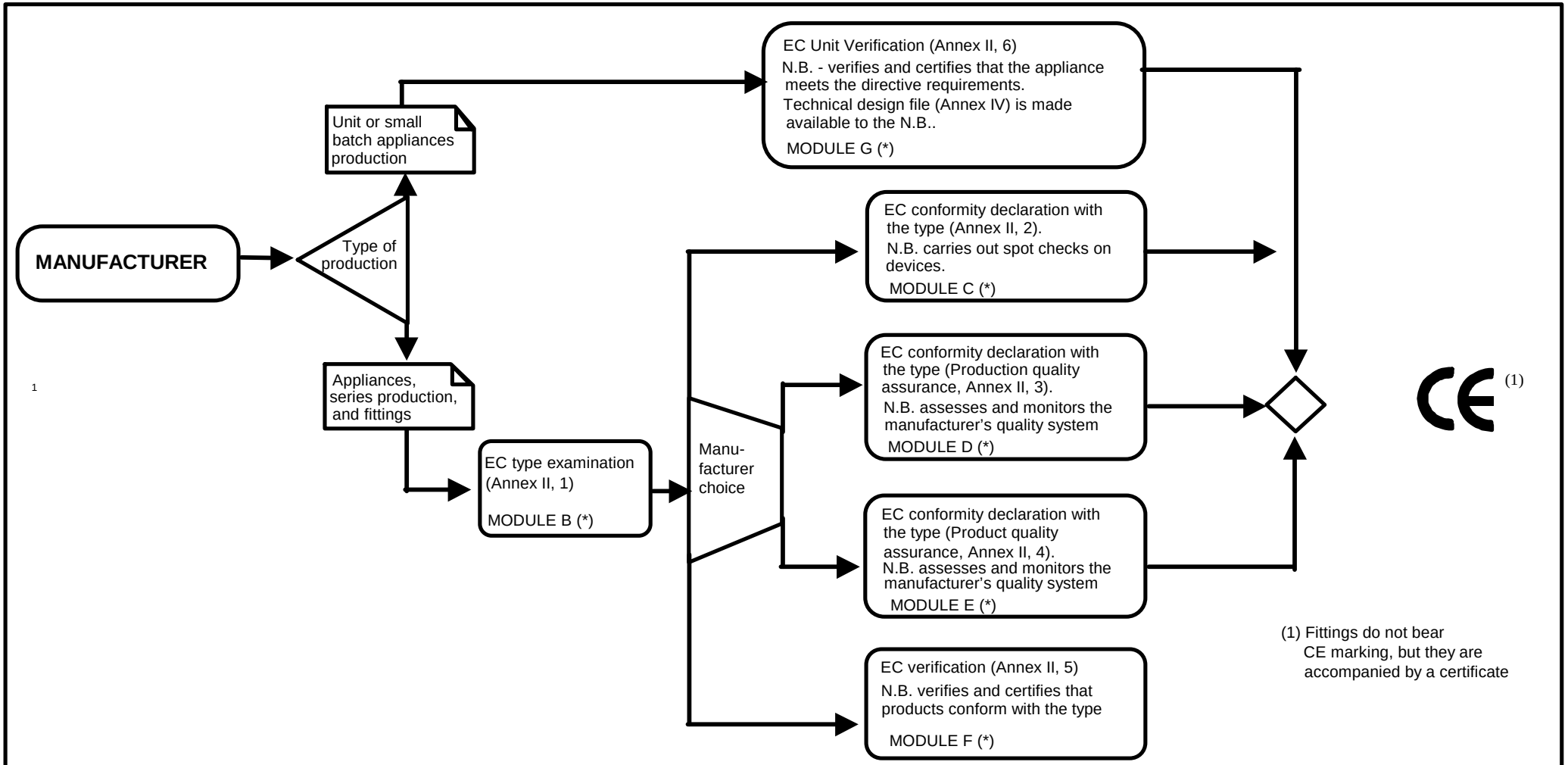
Flowchart for the conformity assessment procedures provided for in the Directive 90/384/EEC on non-automatic weighing instruments

(*) These procedures were approved before the adoption of the Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.



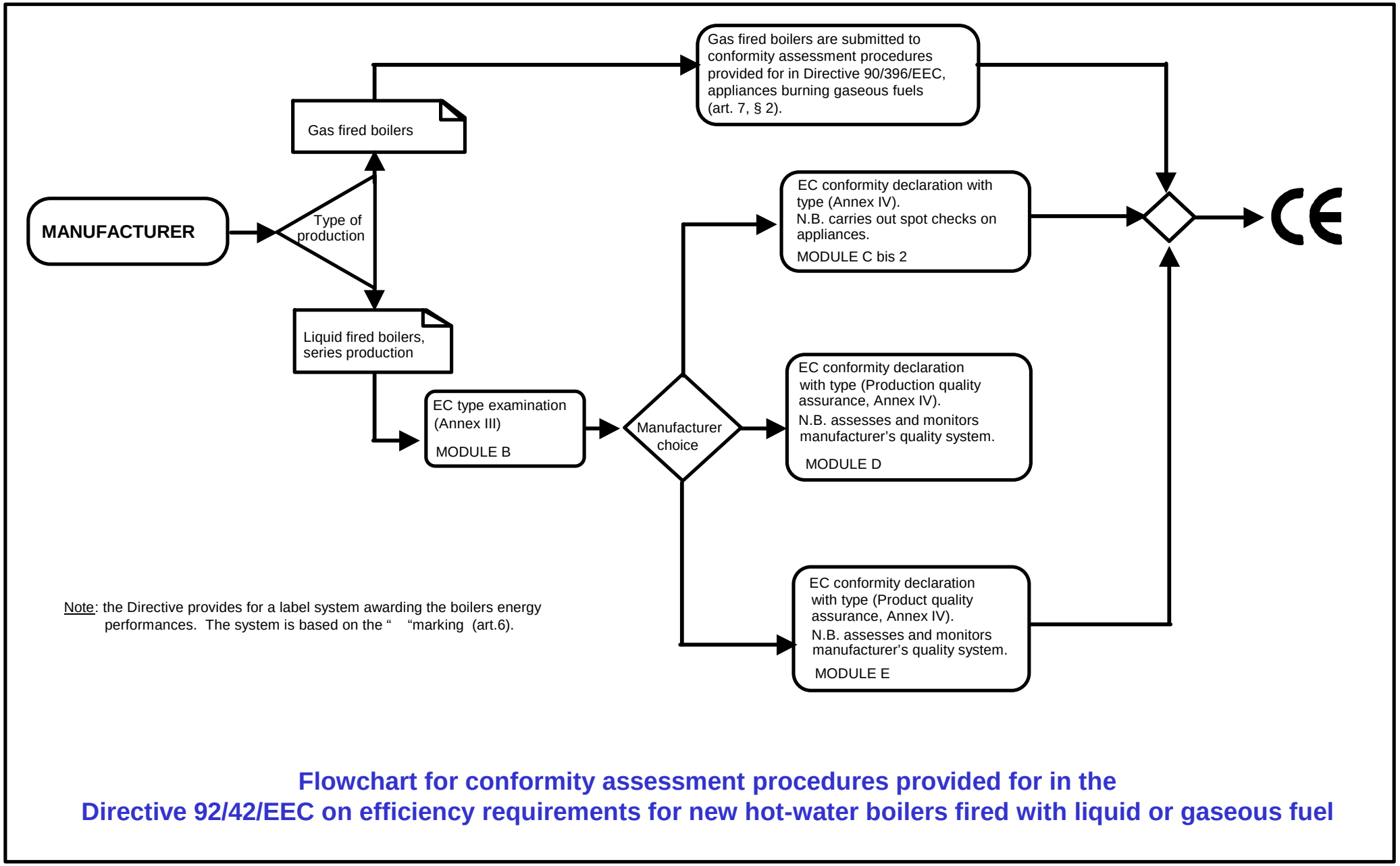
Flowchart for the conformity assessment procedures provided for in the Directive 90/385/EEC on active implantable medical devices

(*) These procedures were approved before the adoption of the Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.

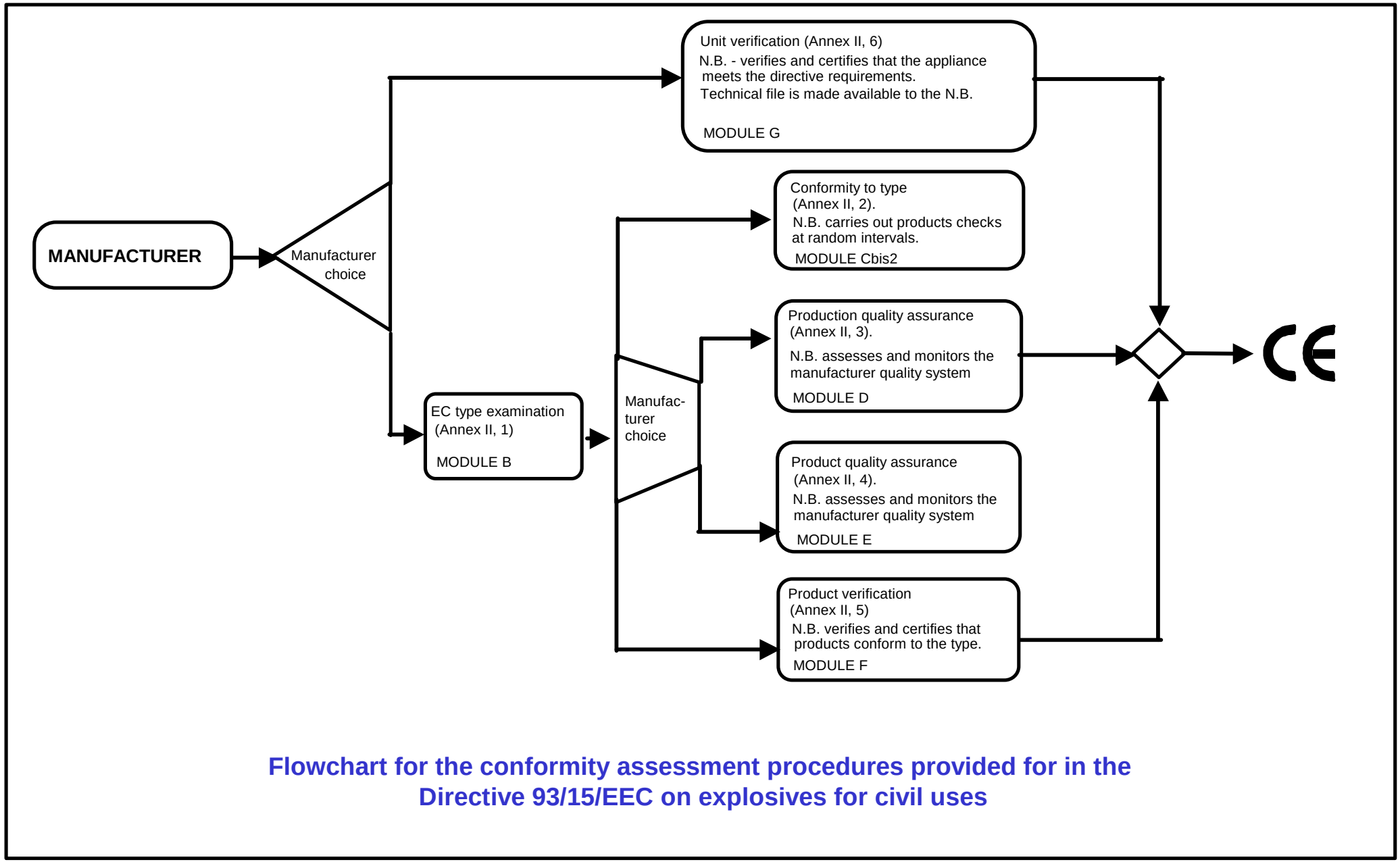


Flowchart for the conformity assessment procedures provided for in the Directive 90/396/EEC on appliances burning gaseous fuels

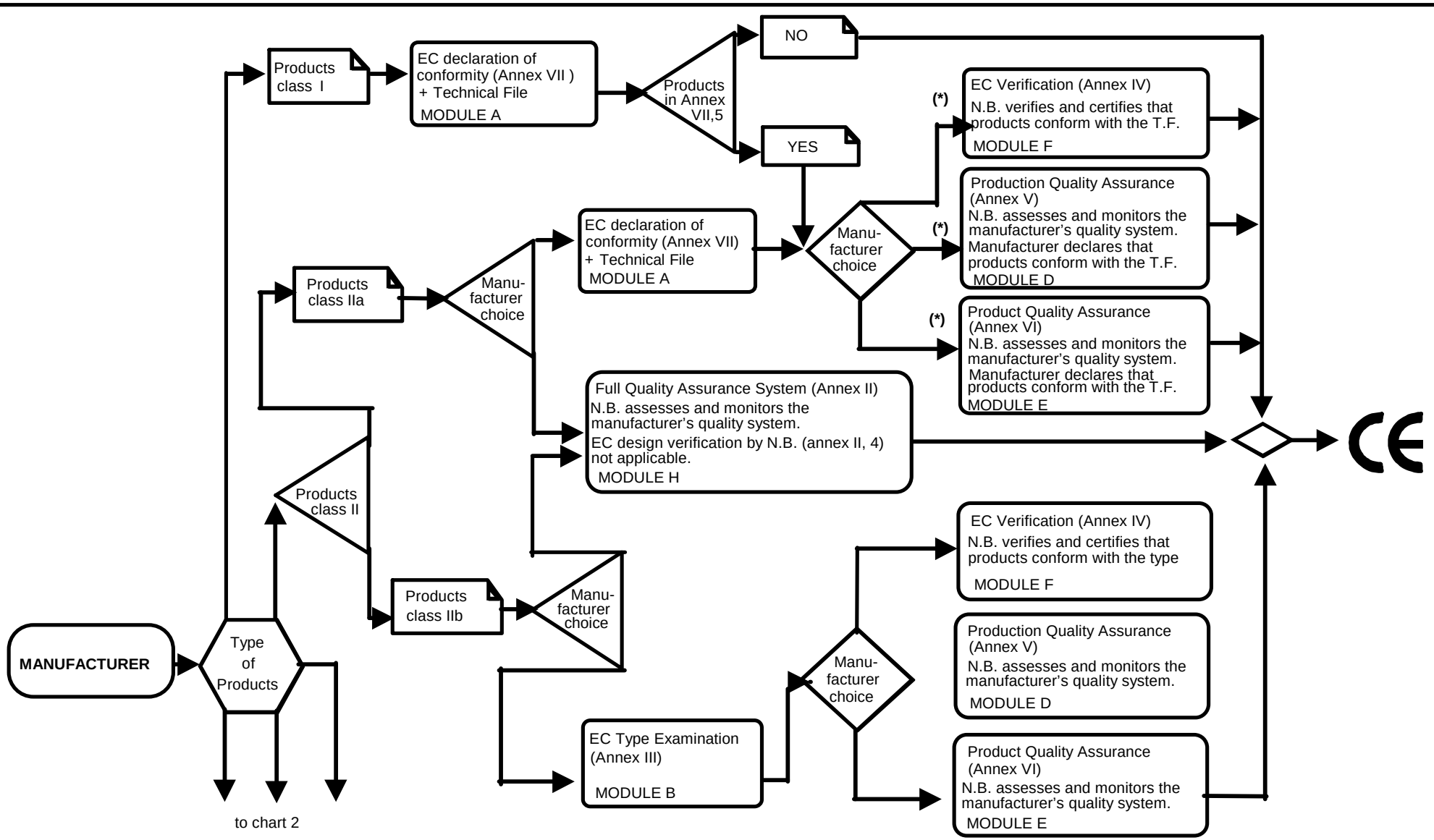
(*) These procedures were approved before the adoption of the Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.



Flowchart for conformity assessment procedures provided for in the Directive 92/42/EEC on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuel



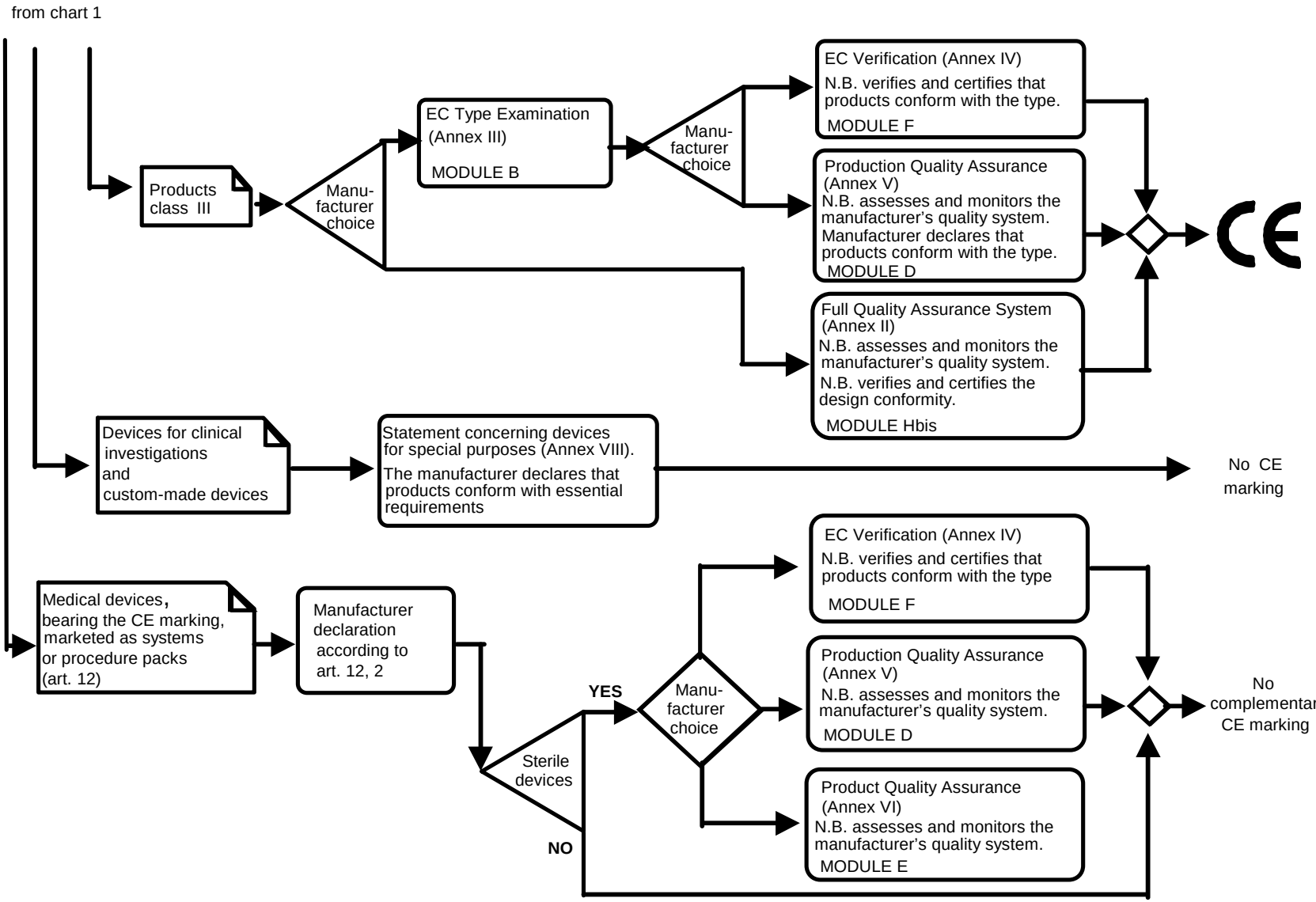
Flowchart for the conformity assessment procedures provided for in the Directive 93/15/EEC on explosives for civil uses



Flowchart for the conformity assessment procedures provided for in the Directive 93/42/EC on medical devices

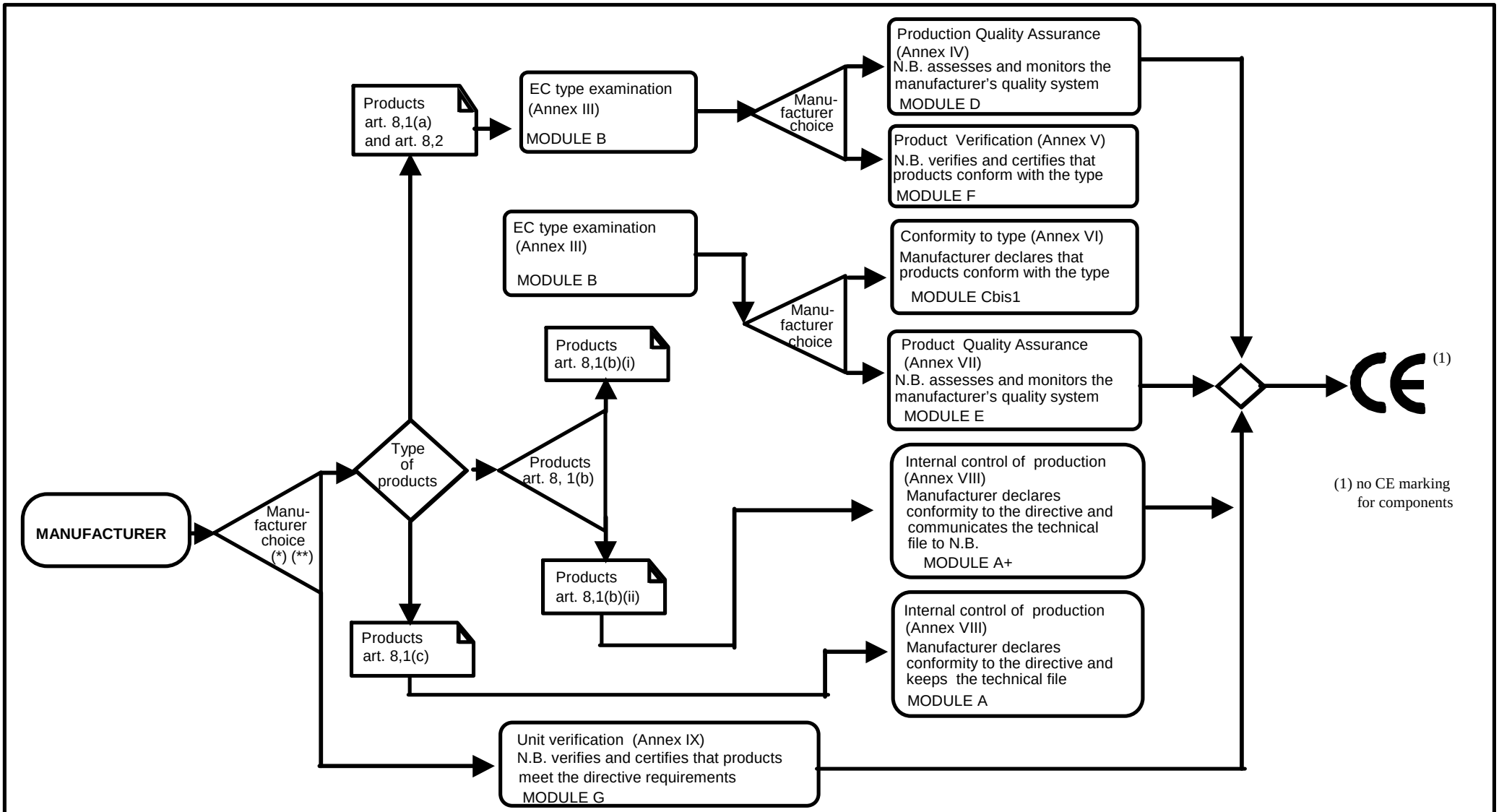
(*) Third party assessment relate to a) obtention of sterile device, b) metrological aspects.

Chart 1 of 2



Flowchart for the conformity assessment procedures provided for in the Directive 93/42/EC on medical devices

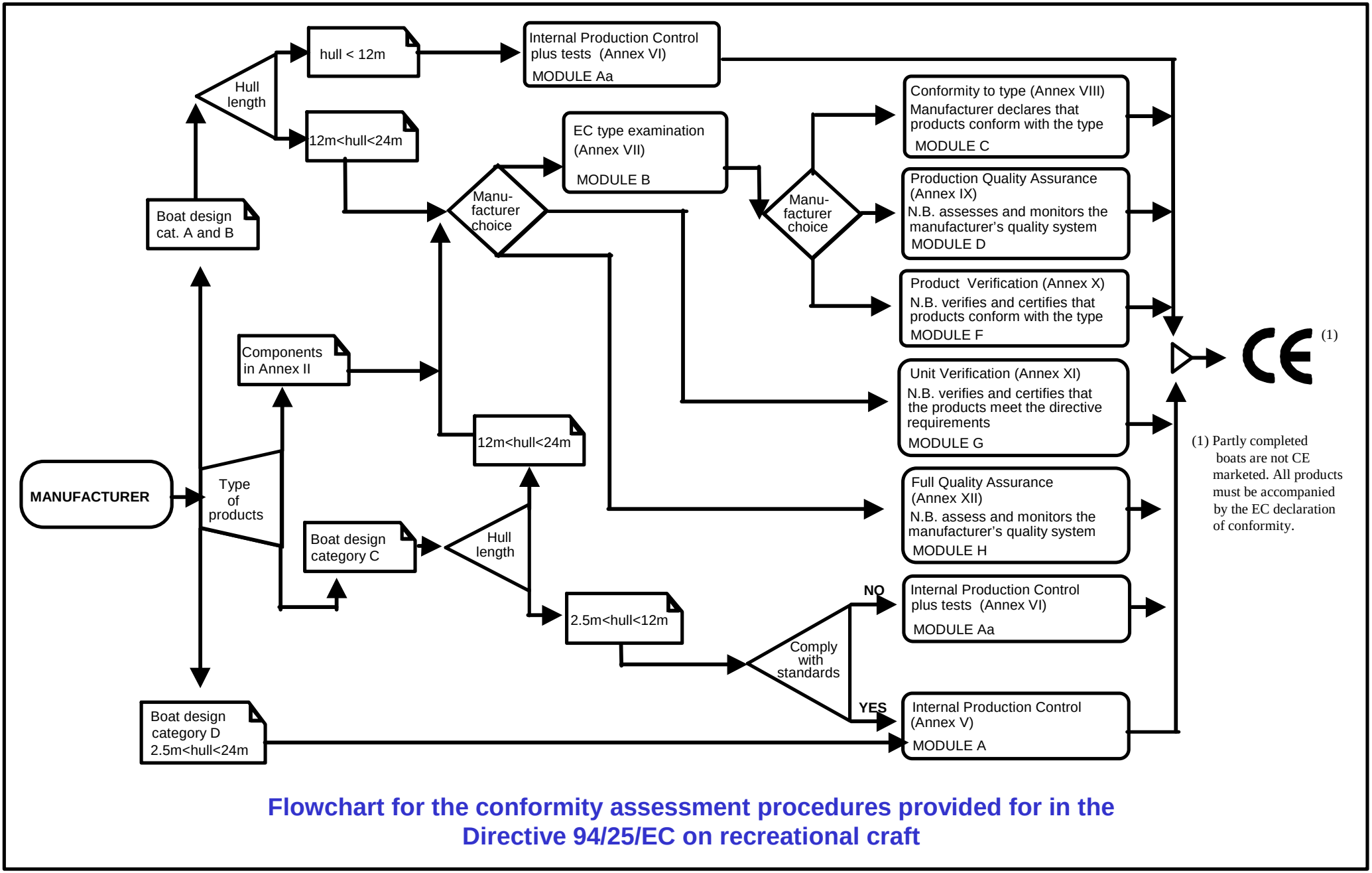
Chart 2 of 2



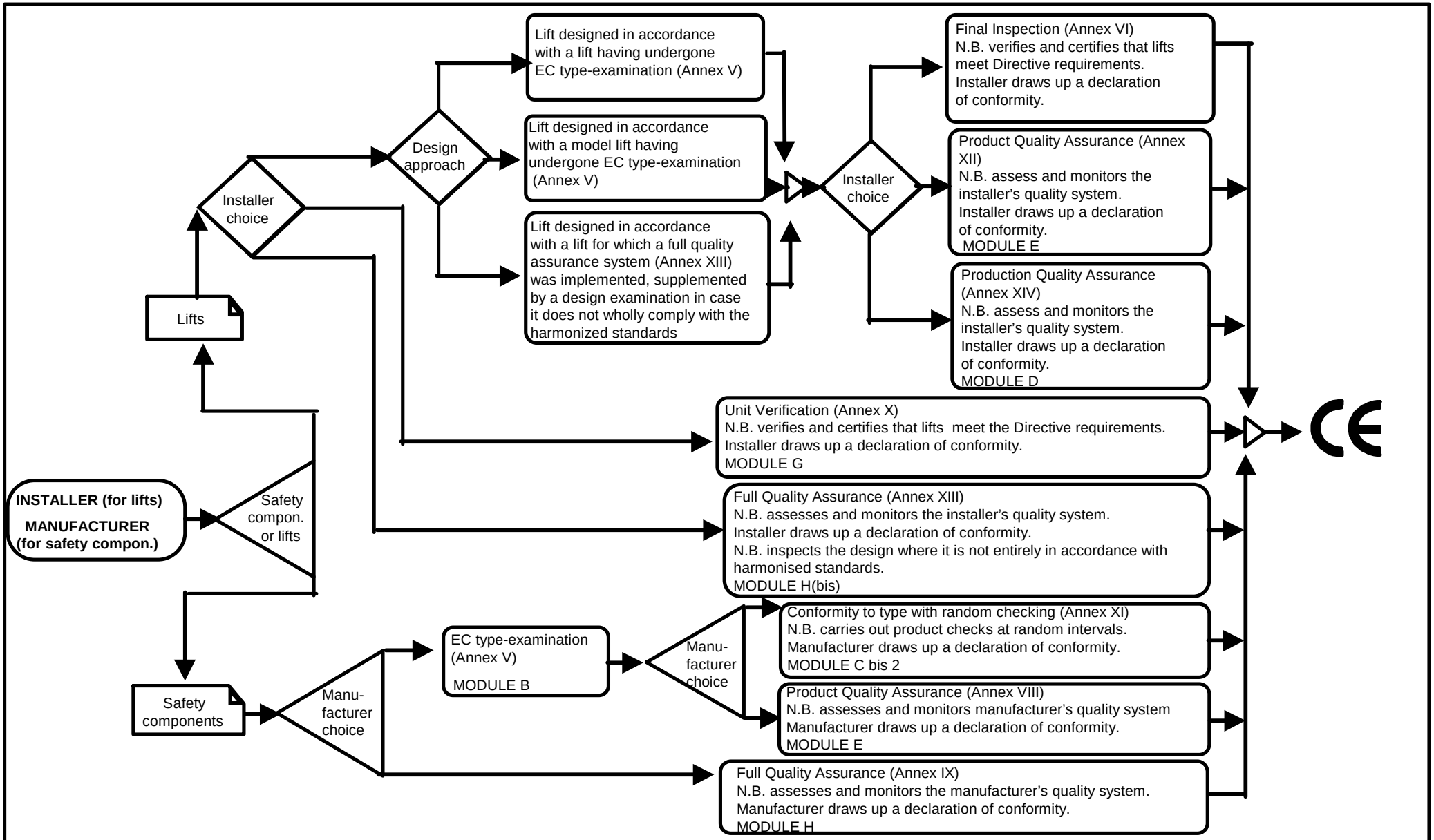
Flowchart for the conformity assessment procedures provided for in the Directive 94/9/EC on equipment and protective systems intended for use in potential explosive atmospheres

(*) All referred procedures shall be applied in respect of components, with the exception of the affixing of the CE marking (art. 8,3).

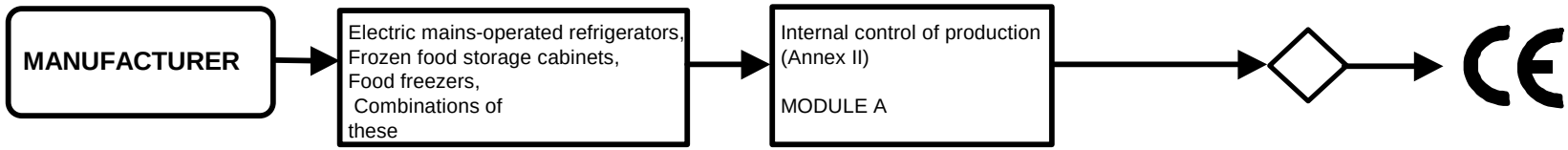
(**) Manufacturer may follow the "internal control of production" (Annex VIII) procedure with regard to the safety aspects referred to in point 1.2.7 of Annex II of the Directive.



Flowchart for the conformity assessment procedures provided for in the Directive 94/25/EC on recreational craft



Flowchart for the conformity assessment procedures provided for in the Directive 95/16/EC on lifts



Flowchart for the conformity assessment procedures provided for in the Directive 96/57/EC on refrigeration appliances

Type of equipment	**Vessels** **Pressure accessories** [1]				**Fired or otherwise heated equipment**	**Piping** **Pressure accessories** [2]			
Fluid to be contained (Art. 9)	gaseous		liquid		Steam or superheated water	gaseous		liquid	
	d [3]	n-d [4]	d	n-d		d	n-d	d	n-d
Annex II : **Tables ® specify categories as a function of PS, V or DN**	1	2	3	4	5	6	7	8	9

Category	**Applicable procedures** (For categories I to IV, the manufacturer must apply one of the modules or one of the modul combinations set out in the relevant category)	**CE-marking**
SEP (Sound engineering practice)	See Article 3.3	NO
I	A ; A1 ; D1 ;E1 ; B1+D ; B1+F ; B+E ; B+C1 ; H ; B+D ; B+F ; G ; H1	YES
II	A1 ; D1 ; E1 ; B1+D ; B1+F ; B+E ; B+C1 ; H ; B+D ; B+F ; G ; H1	
III	B1+D ; B1+F ; B+E ; B+C1 ; H ; B+D ; B+F ; G ; H1	
IV	B+D ; B+F ; G ; H1	

Safety accessories
(Annex II, point 2)

In general :

Category IV

For specific equipment :

Category of equipment to be protected

Assemblies
« Global procedure »
(Art. 10.2)

a) **Each item making up the assembly** :
According to its category ;

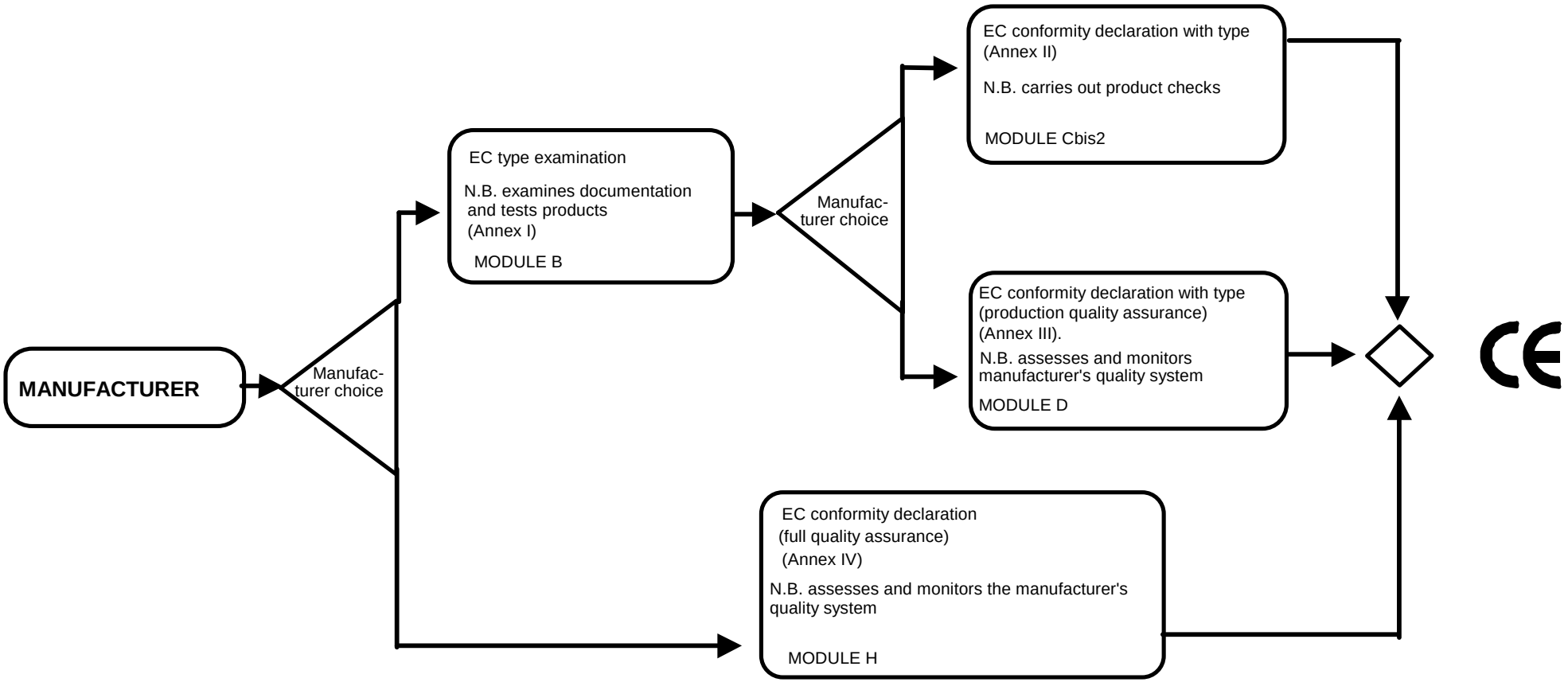
b) **Integration of items :**
According to the highest category of equipment not considering safety accessories ;

c) **Protection of assembly :**
Highest category of equipment to be protected.

CE-marking [5]

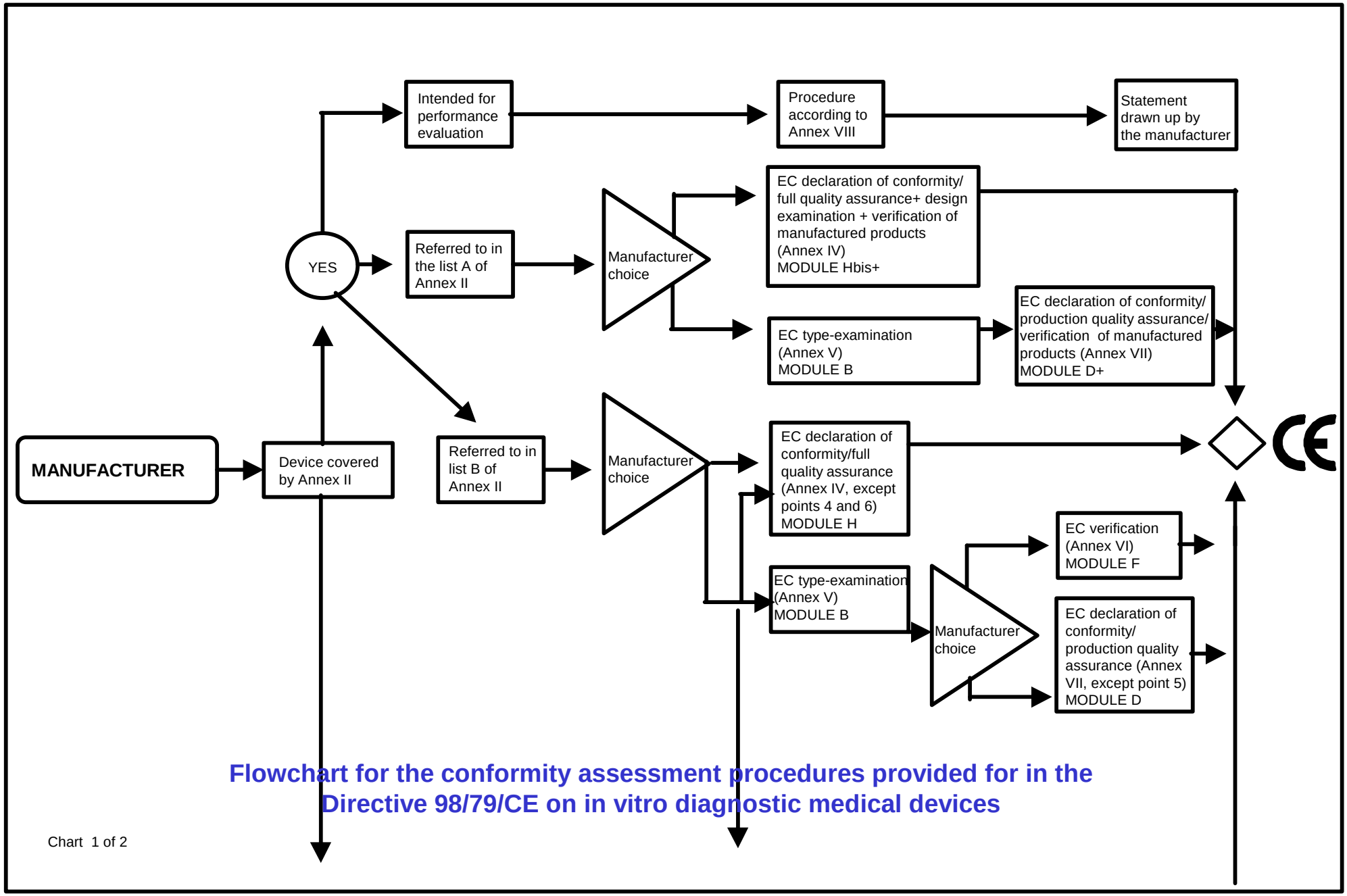
[1] If classified on the basis of PS and **V**. See Annex II, point 3.
[2] If classified on the basis of PS and **DN**. See Annex II, point 3.
[3] "d" means dangerous fluid. See Article 9.2.1.
[4] "n-d" means non-dangerous fluid. See Article 9.2.2.
[5] Within an assembly, CE-marking must not be affixed to each individual item of pressure equipment.

Flowchart for the conformity assessment procedures provided for in the Directive 97/23/EC concerning pressure equipment



Flowchart for the conformity assessment procedures provided for in the Directive 98/13/EC relating to telecommunications terminal equipment and satellite earth station equipment

(*) For specific equipment elements the manufacturer of satellite earth station equipment may use with the internal production control procedure (Module A, Annex IX) as an alternative to the above conformity assessment procedures.



Flowchart for the conformity assessment procedures provided for in the Directive 98/79/CE on in vitro diagnostic medical devices

Chart 1 of 2

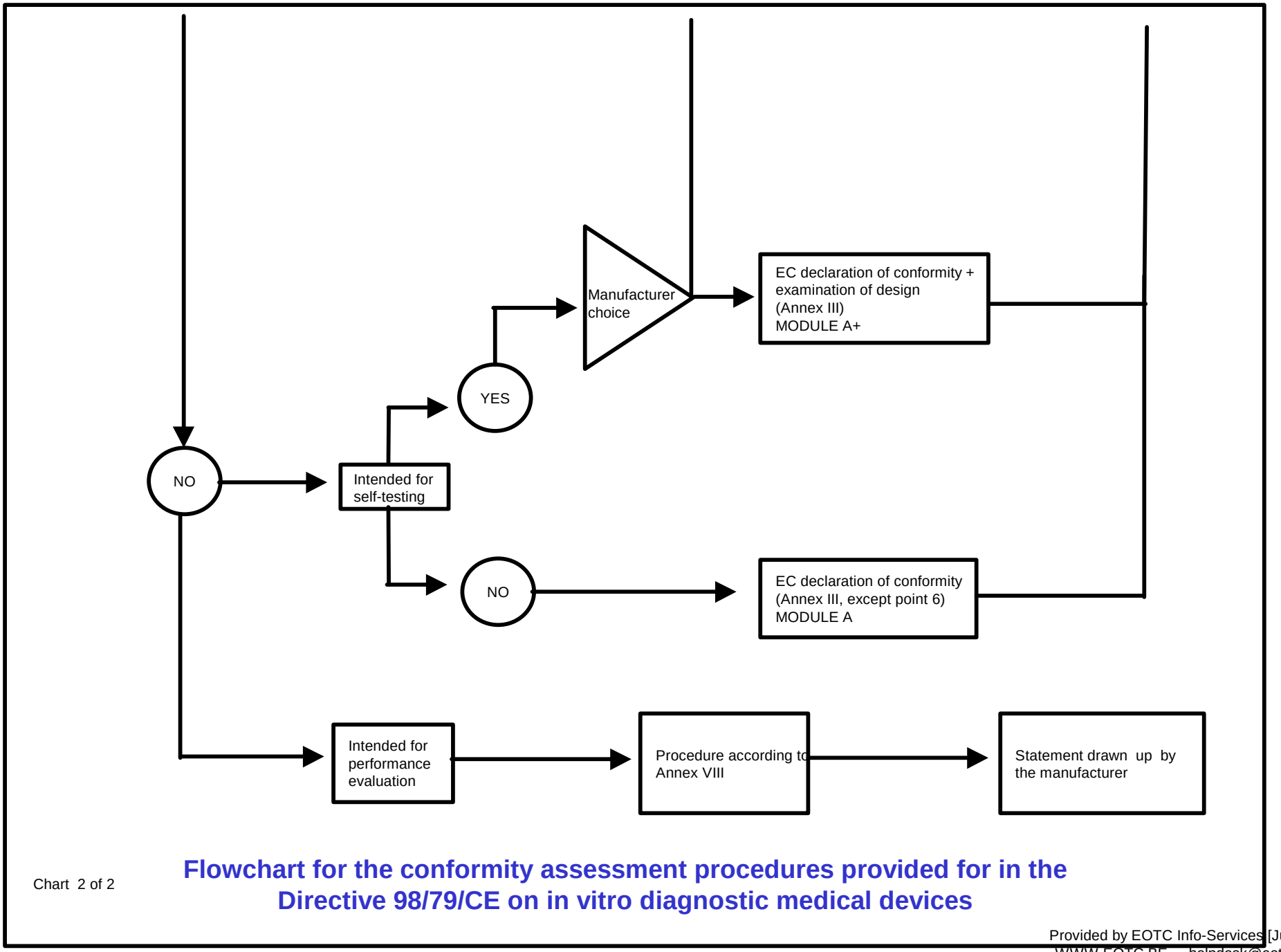
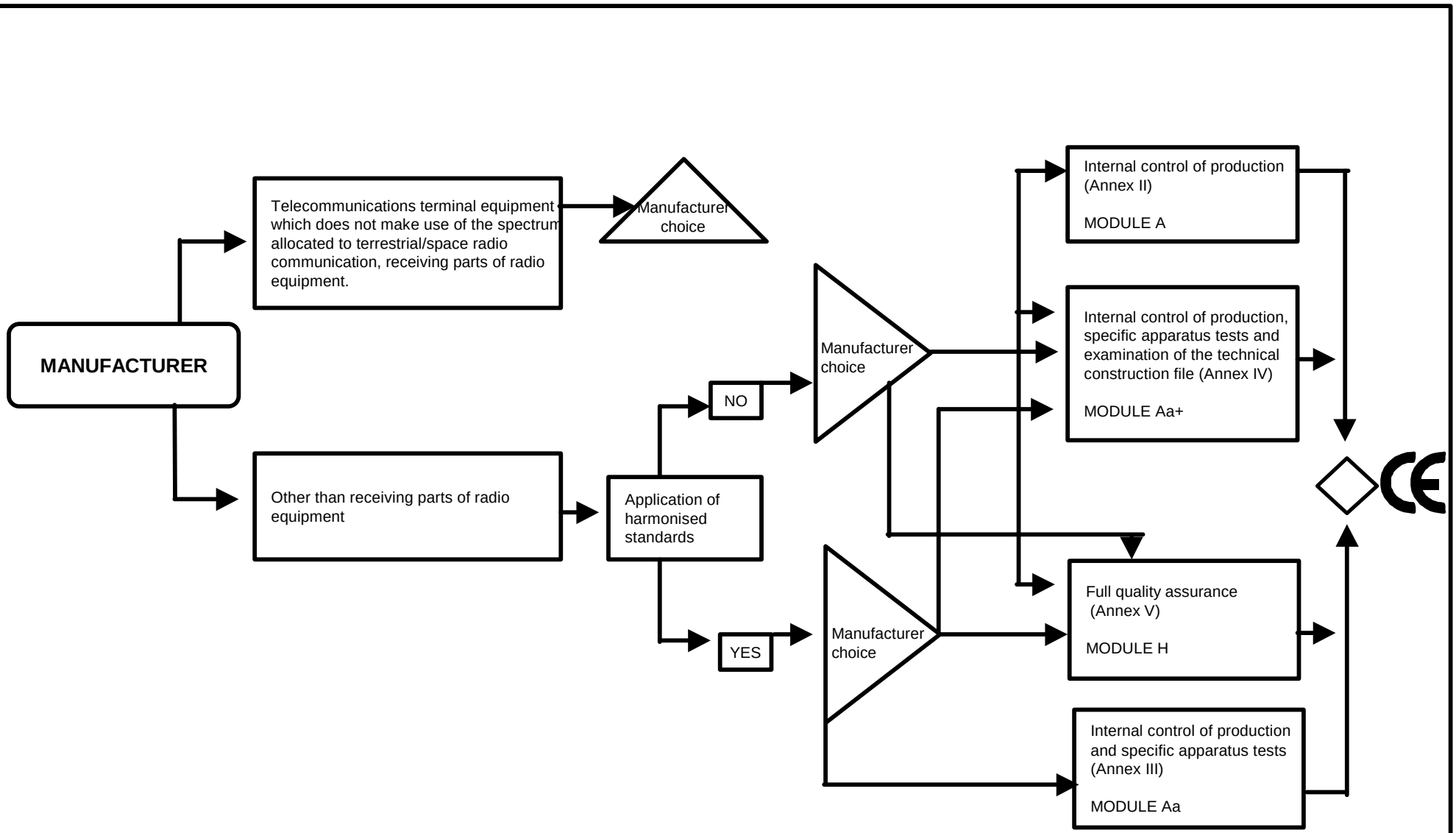


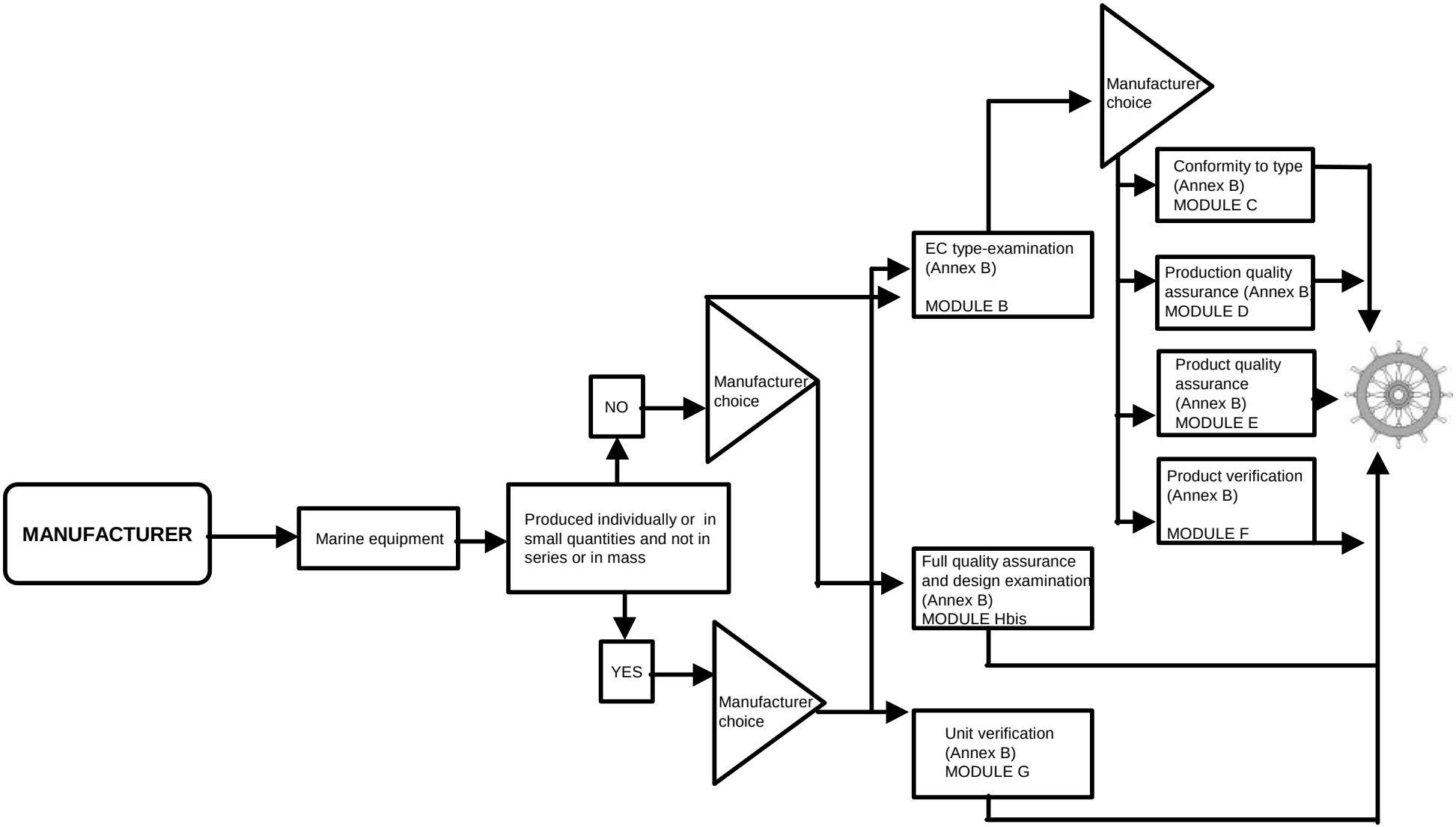
Chart 2 of 2

Flowchart for the conformity assessment procedures provided for in the Directive 98/79/CE on in vitro diagnostic medical devices



At the choice of the manufacturer, compliance with the essential requirements may be demonstrated, as an alternative, using the procedures of the Directives relating to low voltage equipment and electromagnetic compatibility respectively, where the apparatus is within the scope of these Directives (see tables 1 and 4)

Flowchart for the conformity assessment procedures provided for in the Directive 99/5/EC on radio and telecommunications terminal equipment



Flowchart for the conformity assessment procedures provided for in the Directive 96/98/EC on marine equipment