

Keyword	module	quality assurance
	category	
Directive refere	annex III	Article 10 § 1.4

Adopted by CLAI 20/09/2001

Subject: Conformity assessment - Modules adapted to the type of production

Question: The directive defines for each "risk" category several applicable modules.
How are chosen these modules according to the type of production (with QS/without QS - series/unit) ?

Answer The directive offers a great variety of modules which allow the adaptation to all production cases.
It appears, from the modules description, that they are adapted to different types of production, as follows :

	Without QS		With QS	
	Series	Unit	Series	Unit
Cat. I	A			
Cat. II	A1		D1 or E1	
Cat. III	B + C1	B1 + F	B + E B1 + D H	H B1+D
Cat. IV	B + F	G	B + D H1	H1

Anyway, the manufacturer is free to choose the module to be applied.
(As an extreme example, if he manufactures series equipment with QS, he can choose module G).

Furthermore, article 10 § 1.4 states that the manufacturer can also choose to apply a module corresponding to a higher "risk" category (see CLAP 139 - Guideline 2/11).

Modification compared to previous adopted version : Addition of modules H and H1 for serie production in the table and editorial correction on 2004-09-16.