CLAP

FORM N° 32

Version : 5

Directive 97/23/CE

Keywords:

Module	Quality assurance
Category	

Directive reference:

Annex III - 97/23 EC	Article 10.1.4 - 97/23 EC

Adopted by CLAP: 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 module 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).

Futhermore, 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.