

**Directive 97/23/CE****Keywords:**

Module

Design

Manufacturing

Quality assurance

**Directive reference:**Annex III Module H -  
97/23/EC

Annex III Module H1 -97/23/EC

**Adopted by CLAP:****14/11/1996****Subject:** Conformity assessment – Application of modules H and H1**Question:**

Is it possible to apply a module H or H1 when the design and the manufacturing are made by two different entities independent from each other within a same industrial group, each of the entities having a quality system in accordance with the specifications of the directive?

**Answer:**

It seems possible for the application of a module H as for the application of a module D or E to "subcontract" a part of the operations subject to the control (by inspections or by a quality assurance system).

In a same industrial group, we can imagine that a notified body examines the quality systems and audits in parallel the department responsible for the design and the department responsible for the manufacturing but in any case, there shall be a **UNIQUE RESPONSIBLE** for the conformity to the directive for the concerned equipment, which has authority on the two departments.

Modifications compared to the previous adopted version: Editorial correction on 2004-09-16.