

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

Experimental design method

Standard

Directive reference:

Annex I § 2.2.4 - 97/23 EC

Annex I § 2.2.2 - 97/23 EC

Adopted by CLAP:

12/03/1998

Subject: ESR on design – Experimental design method**Question:** May a harmonised standard specify an experimental design method?**Answer:** YES.

Annex I § 2.2.4 allows that the design of an equipment is validated in all or in part, by an experimental method in certain circumstances fixed in annex I § 2.2.2 (see CLAP 53 - Guideline 5/1). It is one alternative of the essential requirement of the directive, which may be, when applicable, amplified in a harmonised standard.

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