

**Guideline**

**4/8**

**CLAP**

**FORM N°158**

**Version : 2**

**Directive 97/23/EC**

**Keywords :** CE design examination

Design

Experimental design method

Conformity assessment

**Directive references:** Annex III Module B1 - 97/23  
EC

**Adopted by WPG:** 27/06/2001

**Adopted by CLAP:** 27/06/2001

**Subject:** Conformity assessment – Tests for the CE design-examination

**Question:** Are tests by the notified body required for module B1?

**Answer:** No.

In contrast to module B, module B1 consists solely of the examination of drawings, calculations and relevant information concerning manufacturing. The experimental design method may not be used in this module. There are no examinations or tests to be performed on a representative example of the production envisaged.

See also CLAP 111 - Guideline 4/5.

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