

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

Technical documentation

Operating instruction

Instructions

**Directive reference:**

Annex I § 3.4 - 97/23 EC

Annex III - 97/23 EC

**Adopted by CLAP:****16/03/2000****Subject:** ESR on manufacturing – Technical documentation**Question:**

In the French version of PED, the term "documentation technique" (technical documentation) is used both in § 3.4 b) "Operating instructions" of annex I and in the different modules for conformity assessment of annex III.

Is it the same document?

**Answer:**

No.

There is a problem of translation: the English version uses the term « technical documents » for § 3.4 b) of annex I (They are the technical documents which are necessary for the understanding of the instructions) and the term « technical documentation » for the documents which are needed for the conformity assessment required in annex III. (See also CLAP 19, CLAP 20 - Guideline 6/2 and CLAP 21 - Guideline 8/3)

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