

Guideline

7/2

CLAP

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Annex I § 4.3 - 97/23 EC

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Subject: ESR on materials – Certification of the quality (assurance) systems of material manufacturers

Question: What is a "competent body" for the certification of the quality (assurance) systems of material manufacturers?

Answer: A 'competent body' for certification of the quality systems of material manufacturers can be any third party body established as a legal entity within the Community which has recognized competence in the assessment of quality (assurance) systems for the manufacture of materials and in the technology of the materials concerned. Competence can be demonstrated, for example, by accreditation.

See also CLAP 86 - Guideline 7/7.

NOTE 1: A body not established as a legal entity within the Community, even if it has a recognition agreement through the International Accreditation Forum, does not comply with the requirements of Annex I section 4.3.

NOTE 2: A notified body may perform this task only if it has a recognized competence in the field of quality assurance, materials and related process technology. For this certification, the possible use of the notification number for PED is irrelevant.

NOTE 3: The certificate of quality system shall make reference to the legal entity established in the Community and its address.

Modification compared to the previous adopted version: Copy of guideline 1/12 (01/03/06).