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Directive 97/23/EC

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	Manufacturer	Quality assurance
Directive references:	Annex I § 4.3 - 97/23 EC	

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Subject: ESR on material – Specific assessment of material producers

Question: The Directive 97/23/CE considers the case of "a material manufacturer who has an appropriate quality-assurance system, certified by a competent body established within the Community and having undergone a specific assessment for materials". How should this requirement be understood in practice?

Answer:

In practice, this requirement is satisfied when the material manufacturer has a quality assurance system of at least EN ISO 9001 type, certified by a competent body (according to the definition given in guideline 7/2) established as a legal entity within the European Community, and when the field of validity of the certification specifies production of material indicating the relevant material types.
The specific assessment of the quality system shall properly cover all the relevant processes and material properties referred to in the material specifications, and attest-ed in the material certificates.

A single reference to section 4.3 of Annex I of PED is not sufficient to validate the quality assurance system of the material manufacturer. The reference document for quality assurance system which has been used shall be identified. Reference to the PED in the quality assurance system certification is not a mandatory requirement.

Note: See also guidelines 7/5, 7/7 and 9/5.

Modification compared to previous adopted version: copy of guideline 7/16 (31/03/06). Editorial modification on 2013-03-07.