

**Guideline**

**G-16**

**CLAP**

**FORM N°X152**

**Version : 1**

**Directive 2014/68/EU**

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**Directive References:** Annex I § 4.3

**Subject:** ESR on material – Specific assessment of material producers

**Question:**

The PED considers the case of “a material manufacturer who has an appropriate quality-assurance system, certified by a competent body established within the Union 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 G-02 (CLAP X139)) 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 attested 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 Guideline G-05 (CLAP X141), Guideline G-07 (CLAP X143) and Guideline I-05 (CLAP X184).