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Keywords :	Manufacturer	Quality assurance
	Material	Technical documentation
	Competent body	Certificate
Directive references:	Annex I § 4.3 - 97/23 EC	

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Subject: Traceability of 3.1 certificate and associated documentation

Question: When an equipment manufacturer receives a certificate type 3.1 according to EN 10204:2004 by the material manufacturer, in pursuance of the third paragraph of section 4.3 of Annex I, what evidence of compliance with these requirements shall be recorded in the technical documentation?

Answer: The equipment manufacturer shall be able to confirm that the material manufacturer's quality system certificate meets the requirements of the third paragraph of section 4.3 of Annex I (field of validity of the certification, range of validity of certification, establishment of the competent body as a legal entity within the European Community, accreditation).

The equipment manufacturer should keep track of such information which may be requested by the market surveillance authority. To fulfil this requirement the equipment manufacturer should keep in its technical documentation the appropriate quality system certificate of the material manufacturer or other equally objective evidence.

See also Guideline 7/2 and Guideline 7/16. Adopted par WGP on 2013-03-07.