



CO-ORDINATION OF NOTIFIED BODIES
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RECOMMENDATION FOR USE

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Annex: VII
Module C2

Clause:

Key words:

Failure of C2 samples, negative conformity assessment results

Question:

What are the necessary actions following negative conformity assessment results when samples are taken as required by Module C2 assessment of homogeneity?

Solution:

The following steps should be taken:

1. Manufacturer asked to investigate the negative conformity assessment result(s) and advise the notified body of their findings.
2. The manufacturer must inform the notified body whether or not they consider the product acceptable without modification or if the product is to be modified, and how.
3. Notified body to then determine what level of additional testing is required.
4. Additional samples requested from the manufacturer and tested under the authority of the notified body.
5. If additional samples pass the required testing, C2 considered completed.
6. If additional samples fail, steps 1 to 4 repeated.
7. If second set of additional samples produce negative conformity assessment results, C2 certification to be withdrawn / not re-issued.

NOTE:

1. If the module C2 notified body is not the module B notified body, module B notified body to be kept informed throughout the process.
2. Notifying authorities to be informed of negative conformity assessment results.