

Guideline

4/2

CLAP

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Annex III – 97/23/EC

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Subject: Conformity assessment - Taking into account the ISO 9001 certification

Question: Can a manufacturer's existing QA certification which is in accordance with the standards EN ISO 9000 be taken into account by the notified bodies when approving QA systems for modules D, D1, E, E1, H or H1 of the PED?

Answer:

A notified body when approving QA systems according to the modules D, D1, E, E1, H or H1 should take into account that the manufacturer already has ISO 9000 certification particularly if it has been certified by an accredited certifying organisation.

However, the notified body has overall responsibility for ensuring that the QA systems satisfy the pressure equipment directive in particular on aspects in pressure equipment technology.

Reason:

Q.A. systems under the modules D, D1, E, E1, H or H1 must cover the technical aspects in relation to the pressure equipment.

Modification compared to previous adopted version: Copy of guideline 4/2 (28/01/99) and editorial correction on 2004-09-16.