

Guideline

D-07

CLAP

FORM N°X108

Version : 1

Directive 2014/68/EU

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Directive References:

Annex I § 1.2

Annex I § 3.4

Annex I § 3.2.1

Subject: Conformity assessment – Operating instructions

Question: Shall the manufacturer of pressure equipment submit operating instructions as part of the conformity assessment by a Notified Body, and shall the Notified Body verify the content?

Answer: Yes.

PED requires the manufacturer to prepare operating instructions (see Annex I section 3.4) and supply them together with the equipment.

Appropriate operating instructions are an essential safety requirement (ESR) and shall therefore be part of the conformity assessment procedure.

When the Notified Body's duty includes performing or monitoring final assessment, it shall verify the existence of operating instructions and check their compliance with the Directive.

When the Notified Body's duty includes design examination, it shall verify that the intended use and residual hazards are described, and are intended to be included in operating instructions.

For modules based on quality systems, the existence of proper procedures to establish the various elements of the operating instructions shall be verified as part of the assessment of the quality system.

See also Guideline H-03 (CLAP X167).