

Guideline

4/7

CLAP

FORM N°198

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Directive 97/23/EC

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Operating instruction

Instructions

Conformity assessment

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Directive references:

Annex I § 1.2 - 97/23 EC

Annex I § 3.2.1 - 97/23 EC

Annex I § 3.4 - 97/23 EC

Annex III - 97/23 EC

Adopted by WPG: 24/05/2002

Adopted by CLAP: 24/05/2002

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 CLAP 21 - Guideline 8/3) 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.

Modifications compared to the previous adopted version: Editorial correction on 2004-09-16.