

Guideline**9/16****CLAP****FORM N°162****Version : 2****Directive 97/23/EC****Keywords :**

Declaration of conformity

Placing on the market

Pressure equipment

Assembly

National regulation

Directive references:

Article 4 - 97/23 EC

Article 5 - 97/23 EC

Annex VII - 97/23 EC

Adopted by WPG: 27/06/2001**Adopted by CLAP:** 27/06/2001**Subject:** New approach – CE declaration of conformity**Question:** Must a CE-marked item of pressure equipment, or an assembly, be supplied with an EC declaration of conformity, when it is placed on the market?

Answer: The manufacturer of CE-marked pressure equipment or assembly should be aware that the declaration of conformity must be made available for national authorities immediately upon request. Otherwise the presumption of conformity as provided for in Article 5, paragraph 1, is in doubt. For this purpose the manufacturer or his authorised representative established within the Community must draw up a written declaration of conformity and keep a copy of it for a period of ten years after the last pressure equipment has been manufactured.

However, Article 4, paragraph 1.1 requires that Member States provide free movement for pressure equipment and assemblies which comply with the PED and bear a CE mark, but there is no provision in the PED that an EC declaration of conformity must be mandatorily supplied with the pressure equipment or assembly in order to comply with the PED.

In addition, the manufacturer should be aware that the declaration of conformity is a helpful document to the distributor or user because it is a summary of design, manufacture and conformity assessment.

The manufacturer should also be aware that some Member States require that the declaration of conformity is available at the user premises at the time of putting into service and for subsequent in-service inspections of the pressure equipment.

The manufacturer should also be aware that the EC declaration of conformity is an essential document for the manufacturer of an assembly into which a CE-marked item of pressure equipment is to be integrated. It is therefore highly recommended to provide the EC declaration of conformity for all products which are intended to be put into service as such, with the product.

NOTE: The EC declaration of conformity does not need to be a separate document; it may be included in the instructions for use.

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