

Guideline

10/7

CLAP

FORM N°238

Version : 2

Directive 97/23/EC

Keywords :

Conformity assessment

Module

Technical documentation

Quality assurance

Directive references:

Annex III Module D, D1 -
97/23 EC

Annex III Module E, E1 - 97/23
EC

Annex III, Module H - 97/23
EC

Annex III Module H - 97/23 EC

Adopted by WPG: 29/04/2003

Adopted by CLAP: 29/04/2003

Subject:

Conformity assessment – Documentation required within the scope of quality assurance modules

Question:

In Annex III, for modules D, D1, E, E1, H and H1, specific documentation is required to be retained for a period of 10 years after the last date of manufacture.

The text specifically requires that 'documentation concerning the quality system' be retained. Does this also include quality records such as material certificates, test reports etc...?

Answer:

Yes

The provisions concerning the retention of records shall be described in the manufacturer's quality system documentation. The description of technical documentation, in section 3 of module A, should act as the guiding principle for the other modules. This includes results of examinations, test reports, material certificates, etc. and has to be kept by the manufacturer, or his authorised representative, for 10 years after the last of the pressure equipment has been manufactured.

See also the Guide to the Implementation of Directives based on New Approach and Global Approach, sub-clause 5.3.

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