CLAP

FORM N°X217

Version : 1

Directive 2014/68/EU

Adopted by CLAP : 27/03/2017

Directive References: Article 14 § 6

Subject: Assessment of modifications for a pressure equipment placed on the market, being integrated into an assembly

Question: An assembly manufacturer may, under its responsibility, modify a pressure equipment constituting an assembly, after the placing on the market of the equipment but before placing on the market of the assembly (see CLAP X101 - Guideline C-19). The modification is to be assessed as part of the global conformity assessment of the assembly (see point 6 of Article 14 of Directive 2014/68/EU). How should the assembly manufacturer handle this modification?

Answer:

The assembly manufacturer shall evaluate the impact of the modification on the original design of the pressure equipment concerned. For this purpose, he must have the original technical documentation of the equipment. If its analysis shows that the modification of the equipment is intended to modify its performance, destination or original type with a significant impact on the applicable essential safety requirements, he shall consider this equipment as a new product. He submits the results of its analysis for validation to the notified body in charge of the conformity assessment of the assembly.

1. If the modified equipment is considered as a new product:

- as part of the global conformity assessment procedure for the assembly, the equipment is subject to a conformity assessment, defined according to its category in accordance with point 6 (a) of Article 14 of the PED and based, where applicable, on the conditions of the assembly;
- it is not necessary for the assembly manufacturer to repeat the conformity assessment actions for the parts not affected by the modification, provided that he demonstrates that the corresponding elements of the original documentation do not require updating.

Note: The original marking and the documents issued by the initial manufacturer and its notified body shall be replaced by those of the assembly manufacturer and its notified body.

2. If the modified equipment is not considered as a new product, the assembly manufacturer:

- attaches to the equipment instructions sent to the end user with the assembly instructions, the technical file of the modification including the description of the modification and justification of the classification of the modification by the manufacturer, validated by the notified body in charge of the conformity assessment of the assembly,
- refers to the EU declaration of conformity of the assembly, a statement that the equipment has been modified and that the relevant documentation is in the equipment instructions.
- unambiguously identifies the modification on the equipment, without altering the dataplate.