

Guideline

H-20

CLAP

FORM N°X230

Version : 1

Directive 2014/68/EU

Adopted by WGP : 13/09/2018

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Directive References: Annex I

Annex III

Subject:

Other ESR – Risk assessment towards PED 97/23/EC

Question:

How do the newly introduced requirements to "analyse the hazards and risks" and make an "assessment of the risk(s)" under the PED 2014/68/EU relate to the requirement for a hazard analysis under the PED 97/23/EC?

Answer:

The newly introduced requirements do not constitute a completely new concept.

These requirements clarify the relevant provisions of the PED adapted to the New Legislative Framework. They better describe the concept that has been and still is underlying the design, manufacturing and conformity assessment process of the PED.

A manufacturer who implemented a hazard analysis according to 97/23/EC and on this basis identified solutions to address the essential safety requirements (see H-04 – CLAP X229) was in fact carrying out a risk assessment as it is required in 2014/68/EU.

Nevertheless, the PED 2014/68/EU explicitly requires that the technical documentation includes a record of the analysis and assessment of the risk(s).