

Guideline

8/11

CLAP

FORM N°215

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Subject: ESR particular – Hazard analysis for products built according to harmonized standards

Question: For products built according to a harmonized standard, is the manufacturer still obliged to perform the hazard analysis required by Annex I preliminary observation 3 of the PED?

Answer: Yes.

The manufacturer has
- first to identify the hazards;

- second to determine those essential safety requirements (ESRs) which apply to his product.

Then, a comparison with Annex ZA of an existing harmonized standard will allow him to decide whether this standard fully covers the relevant ESRs for his product.

See also CLAP 61 - Guideline 8/4.

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