

«Qualified» versus «certified» versus «none of the two»

"Qualified" means:

Directive 2006/42/EC: Lifting accessories and slings (machinery) for helicopter operations

- Placing on the market requires an EC declaration of conformity (EC DoC) by the manufacturer (Annex II).
- Manufacturing on the basis of the best demonstrated available technology, in this case DGUV Information 214-911 and others.
- Not subject to EC type examination procedure as stated in Annex IV and IX.
- Manufacturers must keep thorough documentation and compliance verification in accordance with Annex VII, and guarantee quality assurance as stated in Annex X.
- The manufacturer does not need to be approved (no obligation for an official approval or certification by the authorities).

"Certified" means:

Directive 2006/42/EC: Machinery as described in Annex IV

- EC type examination by a notified body (Annex IX).
- Placing on the market requires an EC declaration of conformity (EC DoC) indicating the TEC (CE plus a four-digit number).
- Manufacturers must keep thorough documentation and compliance verification in accordance with Annex VII, and guarantee quality assurance as stated in Annex X.
- The manufacturer does not need to be approved (no obligation for an official approval or certification by the authorities).

Regulation (EU) 2016/425 on PPE: PPE against falls from a height, risk category III (EASA term: "simple PCDS")

- EU type examination certificate by a notified body (Annex VII, Module C2).
- Placing on the market requires an EC declaration of conformity (EC DoC) indicating the TEC (CE plus a four-digit number).
- Manufacturers must keep thorough documentation and compliance verification in accordance with Annex III and are obliged to operate an approved full quality assurance system monitored by a notified body (Annex VII, Module C2).
- The manufacturer does not need to be approved (no obligation for an official approval or certification by the authorities).

EASA CS-27 or CS-29: Lifting accessories and slings (machinery) for helicopter operations

- Not subject to EASA approval. See Machinery Directive.

EASA CS-27 or CS-29: Any other components and equipment, including complex PCDS

- Major change approval/STC by EASA.
- Application must be presented by an approved design organisation (DO; EASA Part 21 J DOA).
- Minor change approval by an approved DO.
- Manufacturing and placing on the market must be performed by an approved production organisation (PO; EASA Part 21 G POA).
- All parties are obliged to keep comprehensive documentation and compliance verification and to ensure traceability.
- DOs and POs must be approved by EASA or FOCA and undergo several audits per year.

«None of the two» means:

If manufacturers of machinery or of other components or equipment do not fulfil either of the aforementioned prerequisites (plus many other conditions) their products must not be placed on the market.

Any person can become or act as a manufacturer. For the definition of "manufacturer", see Machinery Directive 2006/42/EC, art. 2(i).

Both manufacturers and users run a high risk of liability (helicopter operations are subject to strict liability for the consequences).



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