PZT has been notified according to the new PPE Regulation (EU) 2016/425

Now we are able to certify according to PPE Regulation (EU) 2016/425

On 21 April, the PPE Directive 89/686 EEG will be suspended. From this date on PPE products are then only certified according to the PPE **Regulation (EU) 2016/425**. The marketing of PPE is then only possible for one year without any objection by the market surveillance. Unfortunately, it is still not clear whether the existing certificates remain valid for the time of their original validity, at least until 2023, or if all certificates have to be reissued according to Regulation (as the German directive representative insists). Due to the change of hearing protection from Category II to **Category III**, we believe it will be probable that a rewriting will be necessary. In the case of the ongoing certification work it is possible to issue the certificate according to Directive or Regulation or to issue a combined certificate.

If certification is to be carried out according to Regulation, the documents must also comply with the requirements of the Regulation and the quality assurance. In the new PPE Regulation (EU) 2016/425, **hearing protection is classified in Category III**, resulting in increased quality requirements. The manufacturer decides according to which Modules (C2 or D) the products are to be checked by a Notified Body. The modules require annual reviews.

According to **Module C2** the individual products are to be checked. The scope of the tests is currently being coordinated with all Notified Bodies within the European Working Group VG4.

In the case of the **Module D** procedure, the manufacturing process and quality assurance are audited. This requires a certified quality management system from the manufacturer. The audits are also held annually by a Notified Body.

The Notified Body with whom the Modules C2 or D are carried out may be different from the one which has issued the Type Examination Certificate.

Until 20th April 2018

- **The PPE Directive 89/686/EEC is valid without any restrictions!**
- Products placed on the market before this date still require a EC Type Examination certificate according to PPE Directive.
- It’s also possible to issue new certificates under the PPE Regulation or as a combined certificate according to the Directive and Regulation.
- It will be mandatory for Category III products to make a contract according to Annex VII (product inspection) or VIII (production inspection) with the entity responsible for inspection.

Note: We advise not to produce and store too many user manuals and packaging materials, as these have to be updated according to Regulation (EU) 2016/425 (e.g. Declaration of Conformity, number of the inspecting entity).

From 21st April 2018

PZT GmbH | Am 2016/425 (e.g. 48 E, 26209 Wilhelmshaven, Germany
Telephone: +49 4421 70340 | Fax: +49 4421 70421 | office@pzt-lab.de