

Leakage test

Testing upon delivery

Category 3 on repeat

On 21 April 2018, EU Regulation 2016/425 for Personal Protective Equipment (PPE) came into effect. The regulation promoted hearing protection from category 2 (medium risk) to category 3 (high risk).

As a manufacturer of hearing protection, Elacin must demonstrate the quality of each individual custom-made hearing protector equals the quality of the CE-certified product.

This is assessed by an accredited institute (Notified Body) by means of a supplementary annual procedure.

Elacin has to comply to two components of the EU Regulation:

+ CE type examination according to EN352

+ Annual production control via:

- a. Module C2: mystery shopping by a contracted Notified Body or
- b. Module D: on-site audit by a contracted Notified Body to verify the Production Quality Control System



Elacin has selected Module D and is free to define its own quality system. The Notified Body assesses whether the control mechanisms are sufficient and effective in order to safeguard the quality level of each individually produced custom-made hearing protector.

Outstanding credentials



Since introduction of the new regulation Elacin has passed this audit with outstanding credentials. Without the need to perform a leakage test upon delivery. A leakage test upon delivery is not a standard part of the Elacin quality system¹. Since there are many effective internal control points installed, fit testing would not further contribute to the quality of the custom-made hearing protectors. Other manufacturers may choose a different approach in this respect.

¹ except for Germany due to local legislation

Annual testing or testing upon delivery?

There is a clear distinction between both; while testing upon delivery is a choice of the manufacturer according to the Module D and based upon the control mechanisms (see previous), annual testing is by choice of the employer.



An employer is responsible to perform a risk assessment for all possible hazards in the workplace. Mitigations have to be installed for each identified risk, where source reduction is the preferred route. PPE such as hearing protection assist where source reduction is not feasible. Depending on the occurrence and severity of the risk, the mitigation strategy may offer multiple layers or control points. The risk mitigation strategy is the responsibility of the employer.

Hence, an annual control on the protection performance of hearing protection is not a legal obligation, it is by choice of the employer.

