FAQ 01 with regard to PPE-Regulation
Change of Category for Hearing Protection Products, from Category II to Category III

1) Are other or additional requirements checked in the conformity assessment?

NO, in the tests the requirements according to the standards of the EN 352 series are examined. As long as there are no changes to these standards, the tests will be the same as before. The regulation does not interfere with the test standards.

2) Are there any further documents required for the certification through a Notified Body?

YES, according to Annex III of the Regulation, the technical documentation shall include at least the following elements:

a) a complete description of the PPE and of its intended use;
The intended use declares in what cases the hearing protection should be used and when not.

b) an assessment of the risks against which the PPE is intended to protect;
This is a kind of risk assessment. Further information on risk assessment can be found in Annexes I and II of the Regulation,

c) a list of the essential health and safety requirements that are applicable to the PPE;
This is a list of all relevant test specifications. Alternatively, the Declaration of Conformity can be submitted.

d) design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies and circuits;
The same documents as before: design drawings of the mechanical parts with measurements, complete parts list including all parts of the packaging and user information. For electronic hearing protection: circuit diagrams, assembly diagrams, PCB layout, parts lists.

e) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the PPE;
The same documents as before. Most important for electronic hearing protection is a block diagram with a function description of the circuit.

f) the references of the harmonised standards referred to in Article 14 that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonised standards, the documentation shall specify the parts which have been applied;
This can be summarized together with item c) in one document.

g) where harmonised standards have not been applied, or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;
Usually not applicable.

h) the results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the applicable essential health and safety requirements;
These can be excerpts from the functional and technical specification and results from your own measurements during the development phase.

i) reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class;
Normally these are the reports of conformity checks.

j) a description of the means used by the manufacturer during the production of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class;
Quality inspections must be implemented in the production process. These shall be described in detail in a document.

k) a copy of the manufacturer's instructions and information set out in point 1.4 of Annex II;
The same documents as before.

l) for PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model;
Not applicable for hearing protection.

m) for PPE produced in series where each item is adapted to fit an individual user, a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements.
Custom made earplugs fall into this group. In order to ensure this, among other things, functional tests have to be carried out with every delivered earmold.

3) What happens with the existing Type-Examination Certificates on 21 April 2018?

The type-examination certificates remain valid until the specified expiry date.
Should regulations change, the assessment basis will change and then the certificate has to be adapted. Under certain circumstances, technical checks are required.

4) What about the old Type-Examination Certificates, which do not have an expiration date?

If the test standards do not change or have not changed in the meantime, these certificates remain valid until 2023.

5) Will the Declaration of Conformity be issued in accordance with the Regulation from April 2018?

YES, even if the Type-Examination Certificate, which is the basis for the DoC, has been issued in accordance with the Directive, the Doc shall be drawn up in accordance with the Regulation. Contrary to the past, the DoC has to be published. The operating instructions must contain an internet address, on which the current version is published.

6) Is the marking of the hearing protectors to be changed?

Yes, behind the CE mark, the EU code of the certification body, with which the quality assurance procedure for the product has been agreed, has to be mentioned. It may be a different Notified Body than the one that has certified the hearing protection. For small plugs the marking may also be affixed on the packaging and included in the user instructions.

7) Is printing on the packaging to be changed?

Yes, behind the CE mark, the EU code of the certification body, with which the quality assurance procedure for the product has been agreed, has to be mentioned.

8) What needs to be changed in the operating instructions?

- Behind the CE mark, the EU code of the certification body, with which the quality assurance procedure for the product has been agreed, has to be mentioned.
- The conformity declaration in short form, with an internet address under which the complete Declaration of Conformity can be found shall be added.

9) Are hearing protection products certified according to the Directive included in a product or production inspection?

Yes, the first product tests (Annex VII) must be carried out by April 2019. In the case of a quality assurance of the production process (Annex VIII), the audit must have already been carried out by April 2018, since the products must then be produced in accordance with the Regulation.

10) Do the monitoring contracts have to be concluded with the certification bodies which have also issued the existing Type-Examination Certificates?

No, the manufacturer selects a Notified Body. Of course, only a single Notified Body, especially in the case of Annex VIII.

11) When is a quality assurance according to Annex VII and when according to Annex VIII appropriate?

In principle, the manufacturer decides for one of the two systems. Economic efficiency certainly plays a decisive role here.

12) Does the manufacturer have to maintain a certified quality assurance system?

A quality assurance system must be available, it does not necessarily have to be certified according to ISO 9000. A certified system facilitates the assessment in the case of Annex VIII.