	CO-ORDINATION OF NOTIFIED BODIES **PPE Regulation 2016/425** **RECOMMENDATION FOR USE**	PPE-R/04.045 Version 01

Number of pages: 1	Approval stage : Approved on :
Origin : VG 4 Hearing protection (submitted by BGIA, Germany)	☒ Vertical Group 21.04.2018 ☒ Horizontal Committee 21.04.2018 ☒ EU PPE Working Group 29.11.2019

Question related to ☒ PPE Regulation ☒ EN/prEN: EN 352-2:2002 ☐ Other:

Article: Annex: II, 3.5, III m) Clause:

Key words:

Additional check of protective function, custom moulded earplugs, leakage

Question:

For production of custom moulded earplugs individual imprints of the user's ear canal and pinna are prepared by the manufacturer. Based on this imprint the final PPE is produced by the manufacturer in his premises. About 5 % of custom moulded earplugs show a leakage which results in a significant underprotection as studies showed. How can the conformity with the relevant basic health and safety requirement of the regulation (EU) 2016/425 be tested?

Solution:

The number of cases, where leakage was found, can only by decreased, but never will disappear. As a tension of a facial muscle during preparation of the imprint (duration is several minutes) can not completely be avoided and such a tension can change the shape of the ear canal - e.g. by decreasing of ear canal diameter – the imprint will become too small. The final product will show a leakage and in turn a significant and unknown reduction of the protective function. The user can not compensate the leakage by e.g. deeper insertion as he can do using foam plugs. To guarantee the protective function as specified the only solution is to perform a final check of the function at the user's ear canal by the manufacturer. There are techniques available using e.g. little overpressure or loudspeakers and a probe microphone. During EU type examination such a test has to be applied by the manufacturer as well as the test equipment has to be described by the manufacturer, see Annex III m) of the PPE regulation. The conformity of the description has to be assessed by the notified body during the EU type examination.