



**CO-ORDINATION OF NOTIFIED BODIES**  
**PPE Regulation 2016/425**

PPE-R/04.039  
Version 01

**RECOMMENDATION FOR USE**

Number of pages: 1		Approval stage :	Approved on :
Origin : VG 4 Hearing protection (submitted by INRS, France)		<input checked="" type="checkbox"/> Vertical Group	21.04.2018
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Question related to	<input checked="" type="checkbox"/> PPE Regulation	<input type="checkbox"/> EN/prEN:	<input type="checkbox"/> Other:
Article:	Annex:	Clause:	
Key words: Earplugs, special use, risk in water			
Question: Earplugs are not only used to protect hearing against the harmful effects of noise. Earplugs are also used by swimmers (particularly in swimming pools) against the potential harmful effects of water in this kind of place. The question is: Are earplugs used in swimming pools kind of PPE?			
Solution: The "Guide to application of PPE regulation (EU) 2016/425" (first edition, April 2018) defines in clause 20 (Appendix: Guide for the categorisation of personal protective equipment (PPE)) that "earplugs intended for swimmers to prevent water entering the ears" are not PPE. A certification against the regulation (EU) 2016/425 is therefore not possible. But it might be possible to certify the product in question against the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices because a protection of the middle ear against water while swimming in a pool is necessary, e.g. for individuals with perforated ear drums.			