	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.001 Version 01

Number of pages: 1	Approval stage : Approved on :
Origin : VG 4 Hearing protection	☒ Vertical Group 21.04.2018 ☒ Horizontal Committee 21.04.2018 ☐ EU PPE Working Group

Question related to ☐ PPE Regulation ☒ EN/prEN: 352-1:2002/ 13819-1:2002 ☐ Other:

Article: Annex: Clause: 4.3.8 of EN 352-1, 4.4 of EN 13819-1

Key words:

Earmuffs with different wearing modes, headband force

Question:

The test procedure (measurement of headband force) for earmuffs in different wearing modes has not been specified in sufficient details in EN 352-1 and EN 13819-1. How shall the testing of 'headband force' and 'change of headband force' be performed for earmuffs with different wearing modes?

Solution:

1. When the change in headband force is checked during mechanical tests, the tests shall be performed only with one headband mode.
2. When measurements of the headband force have to be repeated the earmuff shall be allowed to recover for at least 4 hours.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.006 Version 01

Number of pages: 1	Approval stage : Approved on :
Origin : VG 4 Hearing protection	☒ Vertical Group 21.04.2018 ☒ Horizontal Committee 21.04.2018 ☐ EU PPE Working Group

Question related to	☐ PPE Regulation	☒ EN/prEN: 352 (all parts), 13819-2	☒ Other: ISO 4869-1
Article:	Annex:	Clause: 4.2 (of 13819-2:2002)	

Key words:

HPD of particular size, sound attenuation measurement

Question:

How to test hearing protectors of particular size in accordance with EN 13819-2:2002, clause 4.2?

Solution:

VG 4 agrees that, when HPDs of a particular size (e.g. large, small) under EN 352 (all parts) are to be tested, the following protocol should be used:

In the case of an HPD which does not fit all size ranges given in the standard, each test subject shall be asked if the specimen fits. If it does, the test shall be performed. If it does not, the subject shall be rejected from the panel and replacement provided.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.007 Version 01

Number of pages: 1	Approval stage : Approved on :
Origin : VG 4 Hearing protection	☒ Vertical Group 21.04.2018 ☒ Horizontal Committee 21.04.2018 ☐ EU PPE Working Group

Question related to ☐ PPE Regulation ☒ EN/prEN: 13819-1:2002 ☐ Other:

Article: Annex: Clause: 4.6 and 4.7

Key words:

Ear-muffs, drop test

Question:

How shall earmuffs be examined for damage after drop test?

Solution:

When examining an HPD for damage after drop test, if necessary, the cushions and/or liners should be removed before examination and then replaced.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.008 Version 01

Number of pages: 1	Approval stage : Approved on :
Origin : VG 4 Hearing protection	☒ Vertical Group 21.04.2018 ☒ Horizontal Committee 21.04.2018 ☐ EU PPE Working Group

Question related to	☐ PPE Regulation	☒ EN/prEN: 13819-2:2002	☒ Other: ISO 4869-1
Article:	Annex:	Clause: 4.2	

Key words:

Sound attenuation, earplugs in different colours

Question:

Shall sound attenuation measurements be repeated in case an earplug is supplied in different colours?

Solution:

If possible, one measurement should be performed and the samples used for that measurement should include all colours.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.009 Version 01

Number of pages: 1	Approval stage : Approved on :
Origin : VG 4 Hearing protection	☒ Vertical Group 21.04.2018 ☒ Horizontal Committee 21.04.2018 ☐ EU PPE Working Group

Question related to ☐ PPE Regulation ☒ EN/prEN: 13819-2:2002 ☒ Other: ISO 4869-1

Article: Annex: Clause: 4.2

Key words:

Sound attenuation, custom moulded earplugs

Question:

Some types of custom moulded earplugs are offered with a special cream intended to ease the insertion of the earplug into the ear-canal.

Shall sound attenuation measurements be performed using such cream?

Solution:

The sound attenuation measurements shall be performed without the use of such cream.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.010 Version 01

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

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

Article: Annex: II, 1.2.1 Clause:

Key words:

Corded custom moulded earplugs, corded earplugs, earplugs

Question:

By sudden and fast removal of earplugs ear drum ruptures occurred, especially when the cord of corded earplugs was used to remove the earplugs out of the ear canal. What should notified bodies require from the manufacturer to avoid this?

Solution:

The manufacturer should add a warning to the user information: “Warning: Sudden or fast removal of the earplugs out of the ear canal may damage the ear drum.”

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.011 Version 01

Number of pages: 1	Approval stage : Approved on :
Origin : VG 4 Hearing protection	☒ Vertical Group 21.04.2018 ☒ Horizontal Committee 21.04.2018 ☐ EU PPE Working Group

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

Article: Annex: Clause: 4.2.2.4

Key words:

Re-usable earplugs, storage-packaging

Question:

How should a storage-packaging for re-usable earplugs be designed?

Solution:

No recommendation can be given. This must be decided by each notified body from case to case.

CO-ORDINATION OF NOTIFIED BODIES

PPE Regulation 2016/425

RECOMMENDATION FOR USE

PPE-R/04.012

Version 01

Number of pages: 1

Origin : VG 4 Hearing protection

Approval stage : Approved on :

☒ Vertical Group 21.04.2018

☒ Horizontal Committee 21.04.2018

☐ EU PPE Working Group

Question related to ☐ PPE Regulation ☒ EN/prEN: EN 352-3:2002 ☐ Other:

Article: Annex: Clause: 4.3.4

Key words:

Helmet-mounted earmuffs

Question:

A helmet-earmuff combination fulfilling the requirements "adjustability" for M- and L-size has a headband force < 14 N for the M-size, but > 14 N for the L-size. Can this combination be tested and sold as an M-size combination only?

Solution:

It was agreed that such a combination can be tested and sold as an M-size combination only.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.015 Version 01

Number of pages: 1	Approval stage : Approved on :
Origin : VG 4 Hearing protection	☒ Vertical Group 21.04.2018 ☒ Horizontal Committee 21.04.2018 ☐ EU PPE Working Group

Question related to ☐ PPE Regulation ☒ EN/prEN: 352-4:2001/13819-2:2002 ☒ Other: ISO 4869-4

Article: Annex: Clause: ... / 4.3.3

Key words:

Level-dependent earmuffs, MIRE, measurement noise, volume control

Question:

1 Which test method should be used for the testing? Should MIRE (microphone in real ear) or HATS (head and torso simulator) or ATF (acoustic test fixture) technique be used?

2 Which tolerances shall be aimed at for the generation of the L-orientated, M- , and H-orientated noise described in EN 352-4?

3 Which adjustment of the volume control shall be used for the testing of the level-dependent function of the earmuff?

Solution:

1 The MIRE-technique as described in Annex B of EN 352-4:2001 should be used. In the area of the concha, the microphone, including supporting elements and electrical leads, shall occupy an area not exceeding 25 mm² in the plane perpendicular towards the centre axis of the ear canal (this differs from EN ISO 11904-1). The microphone position shown in Figure 1 a) of EN ISO 11904-1:2002 shall be used, i.e. open ear canal and the port of the microphone shows towards the ear drum and the position is in between the ear canal entrance and the ear drum, preferably near by the ear canal entrance in a distance of a few mm.

2 M-noise: L_C-L_A = (+ 2 ± 0,2) dB; H-orientated noise: L_C-L_A = $-1.2^{+0.1}_{-0.2}$ dB; L-orientated noise: $L_C - L_A$ = $+6^{+0.4}_{-0.2}$ dB. Measure in one-third-octave bands and calculate the $L_C - L_A$ value.

3 Adjust to maximum volume.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.017 Version 01

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

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

Article: Annex: Clause:

Key words:

Custom moulded earplugs

Question:

Which qualification is required for a person, who makes impressions of the concha and external ear-canal of the test subjects?

Solution:

It should be carried out by a trained specialist for hearing aids or adequately trained personal.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.019 Version 01

Number of pages: 1	Approval stage : Approved on :
Origin : VG 4 Hearing protection	☒ Vertical Group 21.04.2018 ☒ Horizontal Committee 21.04.2018 ☐ EU PPE Working Group

Question related to	☒ PPE Regulation	☒ EN/prEN: 352-4:2001, 352-8:2008	☐ Other:
Article:	Annex: II, 1.2	Clause:	

Key words:

Level-dependent earmuffs with integrated broadcast-receiver

Question:

How should level-dependent earmuffs with built-in broadcast-receivers be tested?

Solution:

Level-dependent earmuffs with built-in broadcast-receivers should be tested in the following way:

1. as a level-dependent earmuff according to EN 352-4:2001 and

2. as a broadcast earmuff using either signal generators or public broadcast stations applying the MIRE-technique according to EN 352-8:2008.

Within a final test all functions of the earmuff shall be set to maximum volume while the test subject is exposed to a diffuse sound field (according to EN 352-4:2001) at criterion level and simultaneously a public broadcast station or a corresponding signal of a signal generator is received by the specimen under test. The maximum sound level achieved in this test situation has to be determined and assessed.

The manufacturer has to give a warning in the user information: "The audibility of warning signals at a specific workplace may be impaired."

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.020 Version 01

Number of pages: 1	Approval stage : Approved on :
Origin : VG 4 Hearing protection	☒ Vertical Group 21.04.2018 ☒ Horizontal Committee 21.04.2018 ☐ EU PPE Working Group

Question related to ☐ PPE Regulation ☒ EN/prEN: 352-6:2002 ☐ Other:

Article: Annex: Clause:

Key words:

Communication earmuffs with an audio input (by wire)

Question:

How should communication earmuffs be tested? Which requirements shall be fulfilled by these HPDs?

Solution:

One way system:

1. In addition to the requirements found in EN 352-6:2002, Annex B, clause B.3 input voltages shall be given in Vrms.
2. Assessment:
   - In case of an SPL-limitation test the limiter; the mean plus one standard deviation of the equivalent diffuse-field related SPL shall not exceed the level equal to 85 dB(A) minus 3 dB(A).
   - In case of no SPL-limitation test the specification of the manufacturer delivered for the user (e.g. „criterion input voltage level“) in order not to exceed the daily exposure limit. Two warnings have to be given in the user information like „When exceeding the specified limits a risk of hearing impairment exists“ and „This hearing protector may not be used to restore entertainment.“.

Two way system:

Check the additional contribution to the SPL by the transmission via the microphone using an artificial mouth according to ITU-T Recommendation P.50 (03/93) and P.51 (08/96) with speech simulating noise according to IEC 60268-1 from 60 to 100 dB(A) in 5 dB-steps.

The manufacturer has to give a warning in the user information: "The audibility of warning signals at a specific workplace may be impaired."

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.022 Version 01

Number of pages: 1	Approval stage : Approved on :
Origin : VG 4 Hearing protection	☒ Vertical Group 21.04.2018 ☒ Horizontal Committee 21.04.2018 ☐ EU PPE Working Group

Question related to ☒ PPE Regulation ☒ EN/prEN: 352-6/-8/-11:2002 ☐ Other:

Article: Annex: II, 3.5 Clause:

Key words:

Hearing protection device with audio communication

Question:

i) Is a hearing protection device (HPD) with audio communication a hearing protector within the meaning of the regulation (EU) 2016/425?

ii) Is it possible to certify a communication hearing protector without sound pressure limiter limiting the total exposure of the user according to the requirement given in the PPE regulation?

Solution:

i) It is an HPD if the manufacturer declares it and it should meet the requirements of the regulation.

ii) From the technical point of view it is possible to produce every communication hearing protector with a sound pressure level limiter. Therefore in general it should not be possible to certify communication hearing protectors without limiter. In case a specific need exists for no limitation or a limitation at higher values of L_{Aeq} (equivalent continuous A-weighted sound pressure level) than the limit values given by the

essential health and safety requirement „Protection against the harmful effects of noise“, clause 3.5 of Annex II of the regulation (EU) 2016/425 on personal protective equipment,

the use has to be restricted to specific applications. These applications have to be specified in the user information and on the packaging. In addition, an appropriate warning and a description of the measures to be taken by the user is required in the user information in order not to exceed the daily limit value.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.027 Version 01

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

Question related to ☐ PPE Regulation ☒ EN/prEN: 352-8:2008 ☐ Other:

Article: Annex: Clause:

Key words:

Wireless complete hearing protection systems with reproduced sound for entertainment

Question:

These systems transmit signals for example via local induction loaps. How should such products be tested?

Solution:

They should be tested as earmuffs with broadcast receivers (see EN 352-8:2008, 5.2.3).

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.032 Version 01

Number of pages: 1	Approval stage : Approved on :
Origin : VG 4 Hearing protection	☒ Vertical Group 21.04.2018 ☒ Horizontal Committee 21.04.2018 ☐ EU PPE Working Group

Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Annex: II, 3.5 Clause:

Key words:

Earplugs with audio communication

Question:

How shall earplugs with audio communication be tested and assessed?

Solution:

An IEC 711 coupler (now EN 60318-4) with an ear canal extension may be used following the procedures given for hearing aids in the relevant standards (recent recommendation of the PTB expert).

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.035 Version 01

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

Question related to	☐ PPE Regulation	☒ EN/prEN: 13819-2:2002	☒ Other: EN 24869-1:1992
Article:	Annex:	Clause: 4.2.2 and 4.3.2	

Key words:

Test site, reverberation time, level-dependent hearing protector, active noise reduction (ANR) hearing protector

Question:

For testing level-dependent earmuffs according to EN 352-4:2001 or ANR earmuffs according to EN 352-5:2002, MIRE-technique (MIRE: microphone in real ear) shall be used. When applying MIRE technique, is it necessary to limit the reverberation time of the test site under 1,6 s in each of the test bands used as required by EN 24869-1:1992?

EN 13819-2:2002 requires in 4.2.2:

“The required apparatus, including test sites and sound field, is specified in EN 24869-1:1992.”

This standard defines also the reverberation time of the room.

Solution:

The compliance of reverberation time of the test site with the requirement of EN 24869-1 and the necessity of the use of a reverberating room to obtain the high levels (particularly for the L-noise) seems to be incompatible or at least needs special acoustical equipment.

Therefore, the sound field used shall comply with the requirements of EN 24869-1 except clause 4.2.2, reverberation time.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.036 Version 01

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

Question related to ☐ PPE Regulation ☒ EN/prEN: EN 13819-2:2002 ☐ Other:

Article: Annex: Clause: 4.1.4

Key words:

Insertion loss, asymmetric design, electronic earmuffs

Question:

The insertion loss is used to test variations of sound attenuation of the test specimens and to test the effect of conditioning (drop test, head band flexing, water immersion, ...) because conditioned and non-conditioned specimens are tested together. EN 13819-2 does not separate between left and right cups. For specific purposes manufacturers produce electronic earmuffs which show different sound attenuation. This is intended by the manufacturer, e.g. left cup with lower sound attenuation and right cup with higher attenuation and restored communication signals.

The mean is taken over all cups and the criterion is given in EN 352-1 resp. -3 as follows: The standard deviation shall not be greater than 4,0 dB in four or more adjacent one-third-octave bands, and not greater than 7,0 dB in any individual one-third-octave band. This criterion may be not fulfilled by the mentioned special earmuffs although the product shows a good design for a specific purpose.

Solution:

The criterion of EN 352-1 resp. -3 to be used for the insertion loss may be applied separately to left and right cups in specific cases. In such a case the manufacturer has to include a statement (warning) in the user information specifying the special purpose of his product together with all the impacts on the users' safety resulting from the asymmetrical design of the hearing protector.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.037 Version 01

Number of pages: 1	Approval stage : Approved on :
Origin : VG 4 Hearing protection	☒ Vertical Group 21.04.2018 ☒ Horizontal Committee 21.04.2018 ☐ EU PPE Working Group

Question related to ☐ PPE Regulation ☒ EN/prEN: 13819-1:2002 ☐ Other:

Article: Annex: Clause: 5.2.3

Key words:

Nominal size designation, flanged earplugs

Question:

EN 13819-1, clause 5.2 reads: In order to assign a nominal size designation to each earplug, the dimensions of that part or those parts of the earplug that are intended to seal the ear canal are assessed using a gauge comprising a set of circular holes.

Which flanges shall seal the circular hole?

Solution:

At least that flange showing the smallest and that one with the largest diameter shall seal one circular hole.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.038 Version 01

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

Question related to	☐ PPE Regulation	☒ EN/prEN: EN 352-4:2001 EN 352-7:2002	☒ Other: EN 352-1: 2002, EN 352-2:2002, EN 352-3:2002
Article:	Annex:	Clause: 4.3.2 (in both standards)	

Key words:

Level dependent earmuff/earplugs, minimum criterion levels

Question:

Existing standards of the EN 352 series do not specify any minimum protection requirement for level-dependent earmuffs/earplugs when worn (as designed) with the level-dependent mode in operation. In case a level-dependent earmuff/earplug provides sufficient attenuation in passive mode but exposes the user by an internal level of 86 dB(A) where the external level is 83 or 86 dB(A) when operated in level-dependent mode this hearing protector offers a lower level of protection in this mode.

How shall these products be dealt with?

Solution:

All products shall at least have a criterion level (for all test noises H, M and L) of 85 dB(A). This eliminates extreme products that have a very high amplification and/or a very high standard deviation.

In addition to that requirement there are minimum criterion levels derived from the minimum attenuation values for passive HPDs from EN 352-1 to -3 (H = 12 dB, M = 11 dB, L = 9 dB):

Minimum criterion level H: 97 dB(A)

Minimum criterion level M: 96 dB(A)

Minimum criterion level L: 94 dB(A)

(The determination of criterion levels is specified in EN 352-4:2001+A1:2005.)

These requirements shall only be applied for products that are aimed at continuous noise situations. For products that are specifically defined for impulse noise (e.g. for hunters) it is not necessary to meet these criteria.

The criterion levels shall nevertheless be mentioned in the user information with a warning that the product is not suited for high continuous noise levels.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.039 Version 01

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

Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ 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.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.040 Version 01

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

Question related to ☒ PPE Regulation ☒ EN/prEN: 352-7:2002 ☐ Other:

Article: Annex: Clause: 4.1.4

Key words:

Earplugs, non-passive earplugs, special use, impulse noise

Question:

In which way shall the peak attenuation against very high level peak noise of level-dependent earplugs without electronic sound restoration be tested?

Solution:

Note that EN 352-7:2003 does not cover the assessment of protection of earplugs against the risk of exposure to high peak levels.

Measure the peak attenuation on a suitable ear simulator, using an appropriate noise source. The conversion of the measurement data into data characterising the equivalent external impulse sound field may be not straightforward. Only those converted data can be used to compare the exposure under an earplug to peak limit values specified in the EU Directive 2003/10/EC.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.041 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

Question related to ☐ PPE Regulation ☒ EN/prEN: EN 352-6:2002 ☐ Other:

Article: Annex: Clause: Annex B

Key words:

Calculation of mean electrical input level, earmuffs with electrical audio input

Question:

Annex B of EN 352-6 asks for the calculation of the electrical input level for which the mean value plus one standard deviation of the A-weighted diffuse-field related sound pressure level of all sixteen ears is equal to 82 dB(A) .

The procedure to find the mean value is not specified. How should the mean electrical input level be determined?

Solution:

Corresponding to the calculation of the criterion levels in EN 352-4 the following procedure should be applied:

Determine, by interpolation where necessary, the electrical input level (X_i) for which the A-weighted diffuse-field related sound pressure level under the earmuff is equal to 82 dB for each of the 16 ears and then calculate the mean electric input level $(X_1+X_2+...+X_{16})/16$ and the standard deviation.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.042 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

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

Article: Annex: II, 1.3.1 Clause:

Key words:

Banded earplugs worn under the chin, test dimension for sizing

Question:

EN 352-2:2002 specifies only dimensions for “over the head and under the chin” and “behind the head”. How can banded earplugs be tested in case they are especially designed for only “under the chin”? For “under the chin” smaller heights may be appropriate. Which heights shall be required as minimum?

Solution:

An additional specification for “under the chin” banded earplugs is needed.

Use the heads specified in EN 13819-1, figure 11 and add the following test dimensions for the test height (horizontal distance top to hole):

Head A (width 125 mm): 95 mm and 110 mm (chin)

Head B (width 145 mm): 90 mm, 105 and 115 mm (chin)

Head C (width 155 mm): 105 mm and 115 mm (chin)

Head A represents dimensions relevant for the test for the 5th percentile of females and head C represents dimensions relevant for the test for the 95th percentile of males. Anthropometric data used were collected in „Handbuch der Ergonomie mit ergonomischen Konstruktionsrichtlinien, Band 3; Stand: 1989, Zweite, überarbeitete und erweiterte Auflage, herausgegeben von Bundesamt für Wehrtechnik und Beschaffung, Koblenz, Carl Hanser Verlag, München, Wien“.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.043 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

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

Article: Annex: II, 2.9 Clause: 6.2

Key words:

Banded earplugs, exchange of plugs of banded earplugs

Question:

EN 352-2 does not require a description on exchange of plugs of banded earplugs to be included within the user instruction as EN 352-1 does for the exchange of cushions of earmuffs.

Solution:

The manufacturer shall add a description on how to exchange plugs of banded earplugs to the wearer information in case he provides exchange sets for that banded earplugs.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.044 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

Question related to ☒ PPE Regulation ☒ EN/prEN: EN 352-6:2002 ☐ Other:

Article: Annex: II, 1.2 Clause: 4.2

Key words:

Earmuffs with electrical audio input, electrical safety

Question:

For earmuffs with electrical audio input, EN 352-6, clause 4.2 requires: “The electrical circuit of the earmuff shall meet the electrical safety and EMC requirements appropriate to this class of equipment.” Which documents are required and appropriate to check that the requirement given in EN 352-6, clause 4.2 is fulfilled?

Solution:

The change on EN 352-6, clause 4.2 agreed on within the meeting of CEN/TC 159/WG 2 on 2005-11-15 in London was: “The electrical circuit of the earmuff shall meet the appropriate electrical safety and EMC requirements.” A declaration written by the manufacturer may be appropriate (like that one for “suitable constituent materials”).

	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

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.

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Question related to ☒ PPE Regulation ☒ EN/prEN: EN 352-6:2002 ☐ Other:

Article: Annex: II, 3.5 Clause:

Key words:

Earmuffs with communication facilities

Question:

EN 352-6 uses MIRE technique to determine the dependence between the sound level at the ear of the user and the input voltage. Since test subjects are used the maximum level to be reached is 85 dB(A) (diffuse-field corrected). For safety-related communication higher levels may be necessary during work. In order to be able to assess the total sound exposure the user has to know if the product behaves linearily for higher input voltages and if it possible to extrapolate the MIRE data.

How can the necessary additional data be determined and communicated in the user information?

Solution:

The product (all four samples – eight cups) shall be measured with signal input on an ATF (HATS with a coupler according to EN 60318-4:2010) starting with the voltage that resulted in a level of 70 dB(A) with the test subjects. The manufacturer is to be asked for the maximum allowed input voltage. The voltage shall be increased in 5 dB steps up to a diffuse-field corrected value at the ATF of 120 dB(A) or saturation of the signal (or up to the maximum input voltage).

Since the sound levels will typically not be identical to the MIRE results the curve has to be shifted to match the MIRE results for the range where both curves overlap using the following procedure:

- Use the calculation procedure for the criterion voltage (according to RfU 04.041 (latest published online version)) to determine from the MIRE data the input voltage that results in an SPL of 85 dB(A) (diffuse-field corrected).
- For that purpose interpolate for each of the 16 ears the voltage value that results in 85 dB(A). Mean minus standard deviation for the 16 values gives the required voltage, U_{85}.
- Measure all four samples (eight data sets) on the ATF and calculate the mean over the eight values for each input voltage.
- The mean of the values measured on the ATF will probably not contain a data point with the voltage value of U_{85}, therefore determine this point by interpolation.
- Determine the difference between MIRE and ATF values at U_{85}.
- Shift the whole ATF mean curve by this offset.

The combined data from MIRE and ATF shall be presented in the user information as a table (dB SPL vs. U in mV). If a graphical interpolation is wished for the data have to be plotted with a logarithmically spaced voltage axis. To display the whole range of input voltages apply RfU 04.041 (latest published online version) to the MIRE data to get the corresponding voltage values for 70, 75 and 80 dB(A). Moreover the maximum allowed input voltage is to be stated in the user information.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.050 Version 01

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Origin : VG 4 Hearing protection	☒ Vertical Group 21.04.2018 ☒ Horizontal Committee 21.04.2018 ☐ EU PPE Working Group

Question related to	☐ PPE Regulation	☒ EN/prEN: EN 352-5:2002 + A1:2005	☐ Other:
Article:	Annex:	Clause: 6.1 c) and Annex B	

Key words:

Hearing protectors with active noise control

Question:

EN 352-5 does not clearly specify the procedure to calculate the total sound attenuation in the active mode of the ANR HPD. Moreover the user information is not required to contain the total attenuation, only the active values.

How shall the total sound attenuation be calculated and what attenuation values shall be included in the user information?

Solution:

Aim is the calculation of the assumed protection value (APV) of the total (active plus passive) attenuation. It shall be derived by the active attenuation measured according to EN 352-5, Annex B and the passive attenuation determined according to EN 24869-1:1992.

1. Calculate the mean and standard deviation of the active attenuation in one-third-octave bands between 50 Hz and 10 kHz as measured according to chapter 5.2/Annex B of EN 352-5.
2. Interpolate the subjective REAT data (from 16 test subjects according to EN 24869-1:1992) linearly in one-third-octave bands between 63 Hz and 8 kHz for mean and SD. Extrapolate the subjective data to 50 Hz and 10 kHz.
3. Add the mean values of the two contributions (active and passive) to get the mean of the total attenuation for each one-third-octave band.
4. Average the three one-third-octave bands of total attenuation for one octave band (between 63 Hz and 8 kHz) energetically (using negative values, i.e. the residual level under the HPD). The lowest attenuation has the highest weight for the end result. This yields the mean of the total attenuation in octave bands.
5. Sum the standard deviation of passive and active attenuation quadratically for one-third-octave bands between 50 Hz and 10 kHz.
6. Average the three standard deviation values for one octave band (between 63 Hz and 8 kHz) energetically using positive values, i.e. the highest value has the highest weight for the end result. This yields the standard deviation of the total attenuation in octave bands.
7. Calculate the APV for each octave band by subtracting the standard deviation from the mean of the total attenuation.

$$APV_{tot} = m_{tot} - s_{tot}$$

Content of the user information (6.1 c):

The user information shall contain the mean, standard deviation and APV between 63 Hz and 8 kHz for the total attenuation together with the derived HML and SNR values.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.051 Version 01

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Question related to ☐ PPE Regulation ☒ EN/prEN: EN 13819-2:2002 ☐ Other:

Article: Annex: Clause: 5.4

Key words:

Drop test for earplugs

Question:

How many samples should be used for the drop test of earplugs according to EN 13819-2, clause 5.4?

Solution:

All samples that are going to be used for the REAT testing with 16 test subjects should be used for the drop test.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/04.052 Version 01

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Question related to ☐ PPE Regulation ☒ EN/prEN: EN 352-6:2002 ☐ Other:

Article: Annex: Clause: 6

Key words:

Hearing protectors for safety-related communication, user information

Question:

How can it be ensured that hearing protectors for safety-related communication (that do not contain a limiter) are not used for entertainment purposes?

Solution:

An additional warning in the user information should be included that reads:

“This product may not be used for entertainment since the output level is not limited to the necessary innocuous level.”