SLOVENSKI STANDARD
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Varnost laserskih izdelkov - Posebne zahteve za laserske izdelke, namenjene potrošniku

Safety of laser products - Particular Requirements for Consumer Laser Products

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Safety of laser products - Particular Requirements for Consumer Laser Products

To be completed

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This draft European Standard is submitted to CENELEC members for enquiry.
Deadline for CENELEC: 2018-05-25.

It has been drawn up by CLC/TC 76.

If this draft becomes a European Standard, CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CENELEC in three official versions (English, French, German).
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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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European Committee for Electrotechnical Standardization
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European foreword

This document prEN 50689:2018 has been prepared by CLC/TC 76 "Optical radiation safety and laser equipment".

This document is currently submitted to the Enquiry.

The following dates are proposed:

• latest date by which the existence of this document has to be announced at national level	(doa)	dor + 6 months
• latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	dor + 12 months
• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	dor + 36 months (to be confirmed or modified when voting)

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

This standard provides requirements for consumer products containing lasers. The laser beam should always be enclosed so that no eye or skin exposure can occur. However, for some applications the laser beam needs to be accessible. The objective of this standard is to ensure that laser products available to consumers are safe.

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1 Scope

This document specifies the requirements for laser products intended for consumers. The scope of this standard does not include products intended for professional use (non-consumer laser products). That is, non-consumer (professional) laser products are not in the scope of this standard and restrictions as specified in this standard do not apply to non-consumer (professional) laser products.

For non-consumer laser products, compliance with EN 60825-1 is sufficient to achieve the necessary level of safety.

Electric Toys containing lasers, which are covered by EN 62115, are excluded from the scope of this standard.

Class 1C consumer laser products are not in the scope of this standard. For example, cosmetic and beauty care Class 1C laser products are covered by EN 60335-2-113.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 60825-1:2014, *Safety of laser products - Part 1: Equipment classification and requirements*

3 Terms and definitions

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For the purposes of this document, the terms and definitions given in EN 60825-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

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- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
child appealing laser
laser product, including any accessory which can be incorporated later or any attachment which can be fixed later, that resembles by any means another object commonly recognised as appealing to or intended for use by children younger than 51 months, or has entertaining audio effects or animated effects and may resemble cartoon characters, toys, guns, watches, telephones, musical instruments, vehicles, human body or parts of the human body, animals, food or beverages, or play musical notes, or have flashing lights or moving objects or other entertaining features

Note 1 to entry: The emission of a laser beam alone does not make a laser product child appealing.

Note 2 to entry: "Child appealing" depends on a case-by-case assessment of the child appealing character of the product, taking into account the specific characteristics of the product in question (see “New Declaration of ADCO on Child Appealing Appliances, LVDWP/14/4, 15-06-2009).

3.2
consumer laser product
product or assembly of components that constitutes or incorporates a laser or laser system and that is intended for consumers, or is likely to be used by consumers under reasonably foreseeable conditions even though it is not intended for them

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3.3
laser pointer
laser product promoted and intended as a handheld laser either for entertainment purposes or pointing out objects and/or locations

4 Classification of laser products

Laser products in the scope of this standard shall comply with EN 60825-1, including classification, labelling and user instructions.

As a general principle, the product shall be in the lowest feasible class commensurate with the intended function.

5 Child appealing laser products

Child appealing laser products that are not Electric Toys shall be Class 1 laser products.

NOTE: Electric Toys are not in the scope of this standard. Requirements for Electric Toys incorporating lasers are specified in EN 62115.

6 All other consumer laser products

6.1 Generic requirement for consumer laser products

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Consumer laser products shall be Class 1 or Class 2 except as provided in 6.2.

NOTE: Class 1C laser products are not in the scope of this standard, see scope.

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6.2 Speciality products requiring a risk analysis

When the specific application of the consumer laser product requires higher laser classes than specified in 6.1, i.e. higher than Class 1 or Class 2, the following requirements shall be met.

If one or more of the requirements below is not met, then the product shall not be a consumer laser product:

a) The laser product shall not be child appealing, i.e. higher classes are permitted only for a product that is not child appealing;

b) The laser product shall not be a laser pointer, i.e. higher classes are not permitted for a product when it is a laser pointer;

NOTE 1: Laser pointers that exceed Class 2 are associated with a higher risk of causing temporary visual disturbance effects. When persons who are undertaking safety critical tasks, such as driving a car, are exposed to the laser beam resulting in visual glare and visually disturbing effects, this can represent a severe risk. While glare and visually disturbing effects are also possible for lower power lasers, even Class 1 lasers, the effect, for a given wavelength, will be more pronounced for power levels exceeding Class 2.

c) The laser product shall not be of higher classes than Class 1M, Class 2M or Class 3R, i.e. it shall not be Class 3B or Class 4 (see also d for the additional requirement to document the need for a higher class and see e for the requirement of a risk analysis for Class 1M, Class 2M or Class 3R);

d) The need for a higher laser class than specified in 6.1 shall be documented in the user manual as to be necessary for the functioning of the product;

e) A probabilistic risk analysis shall be performed to document an eye injury risk level that is sufficiently low for the application of the respective product, including reasonably foreseeable misuse.

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A probability rate for inducing an eye injury of less than 10^{-9} per hour of using the product is generally considered acceptable for consumer products. In special cases, a corresponding benefit associated to the product, such as for laser distress “flares” used on boats instead of pyrotechnics, can be considered in the risk analysis with respect to acceptable levels of risk.

NOTE 2: A risk analysis with the result of “negligible risk for injury”, however, cannot be the basis for re-classification of the product into a lower class. The classification of the product is to be performed as defined in EN 60825-1 and this does not permit the manufacturer to account for probability of exposure, exposure distance nor user safety measures.

f) Additional wording is required on the explanatory label (Clause 7 of EN 60825-1:2014) to show that risk analysis has been performed and the laser product is suitable for consumer use. Text borders and symbols shall be black on a yellow background. The explanatory label shall bear the words:

SUITABLE FOR CONSUMER USE

Compliance with this standard shall be stated on the explanatory label additionally to the labelling requirements of EN 60825-1:2014, 7.9, by including the designation and the publication date.

An example of the wording for the explanatory label of a Class 3R laser product where the risk analysis demonstrated an acceptably low risk for ocular injury is:

LASER RADIATION

AVOID DIRECT EYE EXPOSURE

CLASS 3R LASER PRODUCT

SUITABLE FOR CONSUMER USE

EN 60825-1:2014

EN 50689:2018

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NOTE 3: An example of a speciality product could be a Class 2M or Class 3R laser distress “flare” provided that all of above requirements are met.

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Annex A
(informative)

Guidance on risk analysis

A.1 Class 1 and Class 2 laser products

For Class 1 and Class 2 laser products, a risk analysis is generally not required in order to decide if they are appropriate as consumer products or not. However, limitations of the classification scheme as described in C.3 of EN 60825-1:2014 need to be considered.

A.2 Class 1M and Class 2M

The concept of Class 1M and Class 2M already inherently includes some risk analysis. These products are associated with negligible risk for injury when they are used in an environment where magnifying optics (binoculars, telescopes) are not employed. That is, when it is not reasonably foreseeable that the laser beam is pointed at a person using magnifying optics then the risk for injury is negligible. Under other circumstances, a formal risk analysis is required in order to decide if the product is appropriate as a consumer product.

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A.3 Class 3R

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Making a Class 3R consumer laser product available on the market needs to be justified. For example, if the same objective can be met with a Class 1 or Class 2 laser product, then Class 3R is not justified.

There is negligible risk for injury of the skin from the optical radiation emitted by a Class 3R laser product.

For emissions with wavelengths less than 400 nm, due to the time-base of 30 000 seconds and the close classification distance, Class 3R laser products with emission exclusively in that wavelength range are usually associated with a very small or negligible risk for injury.

For emissions with wavelengths longer than 1400 nm, due to the safety margin inherent in the accessible emission limit (AEL) compared to injury thresholds of the anterior parts of the eye, together with the close classification distance, as well as aversion responses, Class 3R laser products in that wavelength range are usually associated with a very small or negligible risk for injury.

For Class 3R lasers (both for collimated as well as diverging beams), where all of the following applies:

- continuous wave emission (i.e. no pulsed emission) and
- classified in the wavelength range of 400 nm to 1400 nm and
- based on an AEL where the correction factor C_6 equals unity (C_6=1) and
- where long term viewing is not reasonably foreseeable,

the risk for ocular injury can be assumed to be very low, because exposure levels can be assumed to be below known injury thresholds for the human eye (although the exposure, i.e. the irradiance and/or radiant exposure, might be above internationally agreed and recommended exposure limits, even for short exposure durations such as e. g. 0,25 s).

For continuous emission using $C_6 > 1$ for classification (extended method in EN 60825-1) or for pulsed emission (both when C_6=1 or $C_6 > 1$), it cannot generally be excluded that exposure levels exceed injury

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thresholds of the eye. Consequently, a more detailed risk analysis is needed in order to decide if the product is appropriate as a consumer product.

A.4 Guidance on performing a risk analysis

There are a number of elements to a risk analysis.

For the risk analysis required to demonstrate that a laser product classified as Class 1M, Class 2M or Class 3R is acceptable as consumer product, exposure levels that are reasonably foreseeable for the use of the product as well as for reasonably foreseeable misuse are to be considered.

Failure modes of a product are necessary to be considered in the classification process of the product as required by EN 60825-1. The classification of a given product as Class 3R might be based on the emission during a reasonably foreseeable fault for the case that the emission under normal operation (functioning product with no fault having occurred) is below the AEL of Class 1 or Class 2. In this case the occurrence of the fault has some associated expected frequency which can be considered in a quantitative risk analysis. Classification of a product as Class 3R, based on the emission that is accessible during the fault (where nominal emission is of levels of Class 1 or Class 2) indicates that the risk for injury for the emission under fault is *not* sufficiently low, because when the risk for injury for the emission under fault were below accepted levels for consumers, the fault would be considered "not reasonably foreseeable" according to EN 60825-1 and the class of the product would be based on the nominal emission level (Class 1 or Class 2) and would not be based on the emission during the fault. Consequently, if the risk analysis with respect to the fault was carried out appropriately for classification under EN 60825-1 and the result was a classification as Class 3R based on emission during a fault, then it has to be assumed that the product does not comply with the requirement of acceptably low risk for consumer products.

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Another aspect of the risk analysis is the frequency of expected ocular exposure. If the purpose of the product is to expose people to laser beams, then the expected frequency and duration of exposure will be high. For other products (for instance if they are designed to only point downwards), the lower expected frequency and duration of the exposure can be considered in a risk analysis.

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Relevant parameters that can influence the exposure level are pupil diameter, exposure distance, exposure duration, eye movements and possibly others. Different exposure levels can be associated with the respective frequencies of occurrence, so that worst-case exposure levels have a lower frequency of occurrence and common exposure levels have a high frequency of occurrence.

Exposure levels are usually compared against maximum permissible exposure (MPE) values in order to perform a risk analysis. However, it is possible to consider injury thresholds for a quantitative risk analysis, which are at a higher level as compared to MPE values. It is not possible to specify a "general" margin between the injury threshold for the human eye and the MPE. In some cases, it could be only 2, in other cases it is known to be higher. Using injury thresholds rather than MPE values for a risk analysis is indicated only when there is good confidence regarding the injury threshold, such as derived from high quality scientific studies based on non-human primates models, with an appropriate endpoint, and that is consistent with the overall collection of injury threshold data.

Further general guidance on risk analysis is available in CENELEC Guide 32.