

SLOVENSKI STANDARD oSIST prEN 18165:2025

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Elektronske cigarete in e-tekočine - Zahteve za varnost otrok in preskusne metode

Electronic cigarettes and e-liquids - Child safety requirements and test methods

Elektronische Zigaretten und Liquids für elektronische Zigaretten - Anforderungen an die Kindersicherheit und Prüfverfahren

Cigarettes électroniques et e-liquides - Exigences de sécurité enfants et méthodes d'essai

Ta slovenski standard je istoveten z: o prEN 18165 ovv

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Electronic cigarettes and e-liquids - Child safety requirements and test methods

Cigarettes électroniques et e-liquides - Exigences de sécurité enfants et méthodes d'essai

Elektronische Zigaretten und Liquids für elektronische Zigaretten - Anforderungen an die Kindersicherheit und Prüfverfahren

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European foreword

This document (prEN 18165:2025) has been prepared by Technical Committee CEN/TC 437 "Electronic cigarettes and e-liquids", the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

This document provides an Assessment Tool expressing the rules contained in Clause 6.

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Introduction

This document was developed in response to Article 20(3) of the EU Directive 2014/40/EU Tobacco Products Directive that states: "Member States shall ensure that (g) electronic cigarettes and refill containers are child- and tamper-proof, are protected against breakage and leakage and have a mechanism that ensures refilling without leakage". Additionally, introductory remarks of the Tobacco Products Directive state: "(40) Electronic cigarettes and refill containers could create a health risk when in the hands of children. Therefore, it is necessary to ensure that such products are child- and tamperproof, including by means of child-proof labelling, fastenings, and opening mechanisms".

The document provides methods on how to test and document that an electronic cigarette or refill container is child-resistant and is protected against breakage and leakage.

The purpose is to reduce potential risks for children associated with these products. The identified primary risk for children related to these products is contact with or ingestion of nicotine-containing liquid. Therefore this document applies only to electronic cigarettes and refill containers which contain nicotine or are intended to contain nicotine as part of their normal product lifecycle.

It is important that manufacturers ensure child safety within their products, in the development of electronic cigarette devices as well as refill containers, to make sure that the products are sufficiently child safe if children unintentionally access the devices or refill containers.

To ensure the products are child resistant, the following must be taken into consideration:

- Child appeal;
- Mechanical resistance against breakage and leakage; **Teview**
- Child resistant fastenings and opening mechanisms.

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1 Scope

This document specifies child resistance mechanisms and tests methods for assuring child safety within electronic cigarettes and refill containers.

NOTE Attention is drawn to the definitions laid down in EU Directive 2014/40/EU Tobacco Product Directive.

This document is applicable for electronic cigarettes and refill containers which are containing or intended to contain nicotine.

This document does not apply to tamper resistance nor general product safety requirements which are not specific to child safety.

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 862:2016,¹ Packaging — Child-resistant packaging — Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products

CEN/TS 17287:2019, Requirements and test methods for electronic cigarette devices

EN 60068-2-75:2014, Environmental testing — Part 2-75: Test — Test Eh: Hammer tests

ISO 8317:2015, Child-resistant packaging — Requirements and testing procedures for reclosable packages

ISO 13127:2012, Packaging — Child resistant packaging — Mechanical test methods for reclosable child resistant packaging systems

ISO 28862:2018, Packaging — Child-resistant packaging — Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products

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3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

— ISO Online browsing platform: available at <u>https://www.iso.org/obp/</u>

— IEC Electropedia: available at <u>https://www.electropedia.org/</u>

3.1

child appeal

ability of a product to appeal to children by design or presentation

¹ withdrawn

3.2

electronic cigarette

product, that vaporises e-liquid to generate an inhalable aerosol carried by air drawn through the device by the user

Note 1 to entry: Electronic cigarette is also referred to as e-cig, vapour product, personal vaporizer or ENDS/ENNDS.

Note 2 to entry: Electronic cigarettes differs from tobacco products in that they do not contain tobacco.

3.3

e-liquid

base liquid, which may or may not contain nicotine and/or additives, intended for transformation into an aerosol by an electronic cigarette

3.4

refill container

receptacle containing an e-liquid, which can be used to refill a vaping device

Note 1 to entry: Also called refill bottle.

3.5

open system

refillable electronic cigarette where the user fills/refills a reservoir with e-liquid

3.6

closed system

electronic cigarette with prefilled e-liquid disposable cartomisers or cartridges

3.7

e-liquid reservoir

component for holding e-liquid and supplying it to the atomizer

Note 1 to entry: E-liquid reservoir also refers to tank or reservoir.

3.8

e-liquid cartridge

e-liquid container that can be loaded directly into an e-cigarette, which can be disposable or reusable

3.9

container

vessel of glass, metal, plastic or a combination of materials designed to provide appropriate packaging for a product and having a neck finish suitable for the proper attachment of a closure

[SOURCE: ISO 8317:2015]

Note 1 to entry: In the context of this document, an example of a container would be a refill container without the cap attached.

3.10

closure

cap or securing device of metal, plastic or a combination of materials designed to fit an appropriate container providing a secure seal against environmental challenges

[SOURCE: ISO 8317:2015]

Note 1 to entry: In the context of this document, an example of a closure would be the cap of a refill container.

3.11

child-resistant packaging

package consisting of a container and appropriate closure which is difficult for young children under the age of 52 months to open (or gain access to the contents), but which is not difficult for adults to use properly

[SOURCE: ISO 8317:2015]

Note 1 to entry: In the context of this document, an example of packaging would be a refill container with the bottle and cap combined.

3.12

reclosable package

package which, after it has been initially opened, is capable of being reclosed with a similar degree of security and is capable of being used a sufficient number of times to dispense the total contents without loss of security

[SOURCE: ISO 8317:2015] tps://standards.iteh.ai)

Note 1 to entry: In the context of this document, an example of reclosable packaging would be a refill container with the bottle and cap combined, where the bottle and cap can be reclosed after opening.

3.13

non-reclosable package and ards/sist/957c6139-58fd-48d7-9d63-c40d1948fff8/osist-pren-18165-2025 package or part of a resistant package which, when all or part of the contents have been removed, cannot be properly closed again

[SOURCE: ISO 8317:2015]

Note 1 to entry: In the context of this document, an example of non-reclosable packaging would be a blister pack which, once opened, cannot be resealed. Please refer to Annex C.

4 General requirements

4.1 General requirements

The e-cigarette or refill container shall provide a physical barrier restricting access to e-liquid.

In addition, open systems and refill containers shall have child resistance system functions which adequately control the risk of young children accessing the e-liquid.

The open system or refill container shall maintain the child resistant function of its closure for the manufacturer's specified lifetime.

The lifetime of the open system and refill container is the usage limit that guarantees safety and NOTE performance. It is determined by various factors, such as function, reliability, availability, maintainability, intended

purpose, and risk management. The lifetime will be documented by the manufacturer within their supporting technical documentation.

4.2 Child appeal

Electronic cigarettes and refill containers, including their outer packaging, shall not in any way resemble or incorporate any object commonly recognized as appealing to or intended for use by younger children, The following criteria are regarded as child appealing by themselves and/or in combination:

- exaggerated use of colours;
- coloured lights unrelated to function or excessive in nature;
- entertaining sounds;
- packaging aroma related to food;
- entertaining screen unrelated to function of device or excessive in nature;
- printed images of cartoon character, cosmetic item or food appealing to children on packaging or product;
- product resembles candy;
- shape resembles a toy, weapon, food, cosmetic item, beverage container or animal;
- surface texture is fur, soft squeezable or other child-appealing textures.

Evaluation of child appealing characteristics shall be carried out on a physical sample of the product and by an assessor familiar with the target market of the product, due to local variations in food items and toys.

If the product under evaluation exhibits one of the child appealing characteristics listed above, formal evaluation using the method detailed in 6.1 shall be carried out to assess whether the product meets the threshold for child appeal.

4.3 Mechanical resistance against breakage and leakage

Electronic cigarettes and refill containers shall provide a physical barrier resistant to mechanical stress so that it will not break, crack, or leak when mechanical force is applied to it. To ensure products are sufficiently resistant, the following tests shall be carried out:

- a) Drop test according to CEN/TS 17287:2019 (replicated in Annex A). This involves dropping the sample from a height of (1 000 ± 20) mm onto a concrete surface in horizontal, vertical and angled release configurations.
- b) Impact test according to test Ehb of EN 60068-2-75, the spring hammer test. The sample is rigidly supported and three blows, having an impact energy of 0,5 J, are applied to every point of the sample that is likely to be weak.
- c) Tension test according to Annex B.

The tests shall be carried out on the assembled product. In case of a modular system where no power source is specified, the laboratory shall determine a suitable attachment and note this in the test report. When tested the sample shall not break, crack, or leak liquid.