



**SLOVENSKI STANDARD**  
**SIST EN 17746:2023**

**01-julij-2023**

---

**Elektronske cigarete in e-tekočine - Ugotavljanje konsistentnosti porazdelitve nikotina v določenem zaporedju vdihavanja pri eni e-cigareti**

Electronic cigarettes and e-liquids - Determination of nicotine delivery consistency over defined puff sequences within a single e-cigarette

Elektronische Zigaretten und Liquids für elektronische Zigaretten - Bestimmung der Konsistenz der Nikotinabgabe über definierte Zugsequenzen innerhalb einer einzelnen E-Zigarette

Cigarettes électroniques et e-liquides - Détermination de la constance de délivrance de la nicotine lors de séquences de bouffées définies avec une seule e-cigarette

**Ta slovenski standard je istoveten z: EN 17746:2023**

---

**ICS:**

65.160	Tobak, tobačni izdelki in oprema	Tobacco, tobacco products and related equipment
--------	----------------------------------	-------------------------------------------------

**SIST EN 17746:2023** en



EUROPEAN STANDARD

EN 17746

NORME EUROPÉENNE

EUROPÄISCHE NORM

May 2023

ICS 65.160

English Version

## Electronic cigarettes and e-liquids - Determination of nicotine delivery consistency over defined puff sequences within a single e-cigarette

Cigarettes électroniques et e-liquides - Détermination de la constance de délivrance de la nicotine lors de séquences de bouffées définies avec une seule e-cigarette

Elektronische Zigaretten und E-Liquids - Bestimmung der gleichmäßigen Abgabe von Nikotin über definierte Zugsequenzen einer Anzahl von E-Zigaretten identischen Typs

This European Standard was approved by CEN on 10 March 2023.

CEN 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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

<b>Contents</b>	<b>Page</b>
European foreword.....	3
<b>1 Scope</b> .....	<b>4</b>
<b>2 Normative references</b> .....	<b>4</b>
<b>3 Terms and definitions</b> .....	<b>4</b>
<b>4 Principle</b> .....	<b>6</b>
<b>5 Apparatus</b> .....	<b>6</b>
<b>6 Sampling</b> .....	<b>6</b>
<b>7 Generation of aerosol collected mass for determination of consistency of nicotine delivery</b> .....	<b>6</b>
<b>7.1 Sample preparation for analytical vaping</b> .....	<b>6</b>
<b>7.1.1 General</b> .....	<b>6</b>
<b>7.1.2 Disposable e-cigarettes</b> .....	<b>6</b>
<b>7.1.3 Rechargeable E-cigarettes</b> .....	<b>6</b>
<b>7.1.4 Refillable E-cigarettes</b> .....	<b>6</b>
<b>7.2 Preliminary tests before vaping</b> .....	<b>7</b>
<b>7.3 Vaping and collection of aerosol collected mass</b> .....	<b>7</b>
<b>7.3.1 Vaping plan</b> .....	<b>7</b>
<b>7.3.2 Collection of the aerosol</b> .....	<b>7</b>
<b>7.3.3 Setting up the vaping machine</b> .....	<b>7</b>
<b>7.3.4 Procedure for vaping run</b> .....	<b>7</b>
<b>7.4 Determination of nicotine</b> .....	<b>8</b>
<b>7.5 Determination of nicotine delivery consistency</b> .....	<b>9</b>
<b>8 Test report</b> .....	<b>9</b>
<b>Bibliography</b> .....	<b>11</b>

## European foreword

This document (EN 17746:2023) has been prepared by Technical Committee CEN/TC 437 “Electronic cigarettes and e-liquids”, the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2023, and conflicting national standards shall be withdrawn at the latest by November 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

SIST EN 17746:2023

<https://standards.iteh.ai/catalog/standards/sist/17aac572-f182-4d52-807a-5a6c933429f5/sist-en-17746-2023>

**EN 17746:2023 (E)****1 Scope**

This document specifies the method for the determination of nicotine delivery consistency of an electronic cigarette over the duration of use of e-liquid in the reservoir or a battery charge.

This document:

- defines the equipment to be used;
- specifies the preparation of the e-cigarette samples for testing;
- specifies the aerosol generation process;
- specifies the analytical method;
- specifies the determination of the test result.

This document does not seek to demonstrate whether there is consistency of nicotine delivery between e-cigarettes. The latter is the aim of a separate method under development, EN 17634 *Electronic cigarettes and e-liquids — Determination of nicotine delivery consistency over defined puff sequences of a number of e-cigarettes of identical type* [1]. Two separate methods have been developed to determine consistency of nicotine delivery, pending regulatory clarity on the Tobacco Products Directive's requirement to "deliver nicotine doses at consistent levels" [2].

**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 17375, *Electronic cigarettes and e-liquids — Reference e-liquids*

EN ISO 24199, *Vapour products — Determination of nicotine in vapour product emissions — Gas chromatographic method (ISO 24199)*

ISO 20768, *Vapour products — Routine analytical vaping machine — Definitions and standard conditions*

**3 Terms and definitions**

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

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

- ISO Online browsing platform: available at <https://www.iso.org/obp/ui>
- IEC Electropedia: available at <https://www.electropedia.org/>

**3.1 electronic cigarette**  
**e-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 vapouriser or ENDS/ENNDS.

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

**3.2****e-liquid**

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

**3.3****vaped until exhaustion**

aerosol generation via vaping machine until a pre-determined endpoint

**3.4****open system**

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

**3.5****aerosol collected mass**

ACM

mass of aerosol collected on an aerosol trapping system from the operation of a vapour product by a routine analytical vaping machine after a defined number of puffs

Note 1 to entry: Routine analytical vaping machine is described in ISO 20768.

**3.6****vaping**

action of generating an aerosol with an airflow from an electronic cigarette

**3.7****aerosol**

system of colloidal particles suspended in gas by the use of an e-cigarette

Note 1 to entry: ~~ps:~~ Vapour is a generally accepted, but scientifically incorrect, term for aerosol.

**3.8****nicotine**

(S)-3-(1-methyl-2-pyrrolidinyl) pyridine, conforming to the Chemical Abstracts Service nomenclature under No CAS: 54-11-5

**3.9****clearomizer**

e-liquid reservoir with in-built atomizer

**3.10****e-liquid cartridge**

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

**3.11****coil**

resistive component of the atomiser

Note 1 to entry: Coils are made of metal, ceramic, or other resistive materials.

**3.12****sequence**

defined number of puffs for aerosol generation

**EN 17746:2023 (E)****4 Principle**

The test specimens are vaped until exhaustion (of battery or e-liquid) on a routine analytical vaping machine with simultaneous collection of sequences of aerosol collected mass. If used, the consistency of the laboratory vaping process and subsequent analytical procedures are controlled by using a standardized clearomizer or a reference clearomizer together with a standardized e-liquid as specified in EN 17375. The aerosol collected mass is used for the subsequent determination of nicotine. The determined amount of nicotine per sequence can be used for the statistical determination of nicotine delivery consistency.

**5 Apparatus**

Use the apparatus as defined by EN ISO 24199.

**6 Sampling**

The sample should contain e-cigarettes taken from different parts of the population the study aims to test. Make up the test sample required for the test by randomly selecting e-cigarettes from the different parts of the population represented in the laboratory sample.

**7 Generation of aerosol collected mass for determination of consistency of nicotine delivery****7.1 Sample preparation for analytical vaping****7.1.1 General**

For the overall protocol, at least 5 test e-cigarettes are needed: 2 for the determination of the required number of puffs per sequence and 3 for the determination of the nicotine delivery consistency.

It is recommended to prepare at least two more e-cigarettes in the same way for redundancy in case any problems occur during testing.

**7.1.2 Disposable e-cigarettes**

For testing disposable e-cigarettes, a fresh e-cigarette shall be taken from an unopened pack.

**7.1.3 Rechargeable E-cigarettes**

For any e-cigarettes equipped with rechargeable batteries ensure that the battery is fully charged following the instructions for use.

**7.1.4 Refillable E-cigarettes**

For any e-cigarettes with the e-liquid supplied in pre-filled e-liquid cartridges a new e-liquid cartridge shall be taken from an un-opened pack and inserted into the e-cigarette following the instructions for use.

Any e-cigarettes designed for individual filling (open systems) shall be filled with the type of e-liquid specified in the e-cigarette's instructions for use. If no specific e-liquids or e-liquid characteristics are specified, one of the standard liquids as specified in EN 17375 shall be used. The e-cigarette shall be filled to its maximum level following the instructions for use.



## 7.2 Preliminary tests before vaping

The following tests shall be performed prior to the vaping process:

- a) check the e-cigarette for any leakage;
- b) make sure that the battery works;
- c) for manually filled e-cigarettes note the amount of liquid filled (in mg);
- d) the e-cigarette shall be primed in accordance with its instructions for use. If no specific instructions are provided, the first 5 puffs shall be puffed to waste prior to the first weighing of the e-cigarette;
- e) weigh the filled e-cigarette prior to vaping to the nearest 1 mg.

## 7.3 Vaping and collection of aerosol collected mass

### 7.3.1 Vaping plan

E-cigarettes with a fixed power setting are to be tested as they are. E-cigarettes with adjustable power settings shall be tested using the settings recommended by the instructions for use or if not available, with feasible minimum and maximum power setting. Every test shall be replicated using a second e-cigarette.

### 7.3.2 Collection of the aerosol

Collection of aerosol and determination of nicotine in the aerosol, shall be performed in accordance with EN ISO 24199.

### 7.3.3 Setting up the vaping machine

Set up the vaping machine in accordance with the manufacturer's instructions for use. Puff volume, puff duration and the puff period settings shall be in accordance with the standard conditions given in ISO 20768.

### 7.3.4 Procedure for vaping run

#### 7.3.4.1 General

Insert the e-cigarettes to be tested into the e-cigarette holders. Avoid any leaks or deformations. Any e-cigarettes found to have obvious defects shall be discarded and replaced by prepared spare e-cigarettes.

Ensure that the e-cigarettes are positioned correctly so that the axes of the mouthpiece coincide with the axes of the ports. If available or needed adjust the position of each e-cigarette support and push button activator, following the user instructions given by in the vaping machine manual.

#### 7.3.4.2 Determination of sequence size

Start the vaping process as described in ISO 20768. After 20 puffs stop the vaping process, remove the aerosol trap. Weigh the e-cigarette or the filter trap to the nearest 1 mg and, based on the differential with the pre-vaping weight, estimate the e-cigarette aerosol delivery. The number of puffs per sequence is chosen based on the expected amount of aerosol from the e-cigarette and taking into account the aerosol collection method and the analytical method for nicotine. A recommendation is given in Table 1.

**Table 1 — Determination of number of puffs per sequence**

Per puff delivery of aerosol collected mass	Recommended number of puffs/sequence
≤ 15 mg/puff	20
> 15 mg/puff, ≤ 30 mg/puff	10
> 30 mg/puff	5

Discard the aerosol trap used for the pre-test from further analysis and replace it by a freshly prepared one (gloves shall be worn). Adapt the number of puffs to be captured in the aerosol trap.

#### 7.3.4.3 Vaping run

Prepare a new e-cigarette in accordance to the mentioned procedure. Re-start the vaping process with the identified number of puffs per sequence. Replace the aerosol trap after every sequence by a freshly prepared one.

Immediately after removing from the machine, weigh the aerosol traps to the nearest 1 mg. Note the result and seal the traps with suitable caps. Calculate the differential weight between the loaded and unloaded trap.

For open systems, repeat the procedure until the conditions for refilling of the e-liquid reservoir as indicated in the instructions for use are reached. If there are no related instructions, then repeat until more than 75 % of the weight of added e-liquid has been consumed as per e-cigarette mass loss. The last sequence has to be discarded. If the battery exhausts before this point is being reached, fully re-charge the battery and continue the test. The related sequence shall be discarded as well as the last sequence during which the 75 % of mass loss has been determined. Note the number of valid sequences and keep the traps sorted in regards. Manufacturers would need to establish specification as part of product due diligence.

For non-refillable e-cigarettes, repeat the procedure until the conditions described in the instructions for use have been reached indicating the cartridge needs replacing, or the e-cigarette has reached end of the cartridge or the e-cigarette needs replacing. The last sequence shall be discarded. If there is no clear description of such conditions in the instructions for use, or if the instructions rely on the change in taste of the vape, the procedure shall be repeated until the battery charge has run out as indicated by meeting the relevant conditions from the instructions for use. If there are no instructions on when the battery charge has run out, or only instructions related to taste of the vape, the procedure shall be repeated until the mass loss of the e-cigarette, or the mass captured in the aerosol trap, per sequence has fallen to below 10 % of the mass of the first measured sequence for the e-cigarette. In the cases where the procedure was repeated till the battery charge ran out, or the aerosol delivery decreased to less than 10 %, the total aerosol delivery of the e-cigarette shall be estimated using the total mass loss of the e-cigarette, or the total of the aerosol collected mass captured in the various aerosol traps over the whole procedure. Cumulative aerosol delivery per sequence shall be calculated and all sequences that delivered aerosol past 75 % of the estimated total aerosol delivery, shall be discarded.

Also weigh the e-cigarette to the nearest 1 mg before and after any sequence. Calculate the differential weight and the ratio of the e-cigarette mass loss to the aerosol collected mass for the individual sequence. Unusually high ratios are an indication of e-cigarette leakage or other issues that invalidate the result for that sample. Therefore, if this ratio represents a statistical outlier for at least 2 sequences, the test shall be repeated with a new e-cigarette.

#### 7.4 Determination of nicotine

The determination of nicotine shall follow the procedure described in EN ISO 24199.