SLOVENSKI STANDARD
SIST EN 16679:2015

01-marec-2015

Embalaža - Značilnosti preverjanja nedovoljenega poseganja v embalažo za zdravila

Packaging - Tamper verification features for medicinal product packaging

Verpackung - Merkmale zur Überprüfung von Manipulationen an Arzneimittelverpackungen

Emballage - Témoins d'effraction pour emballages de produits médicinaux

Ta slovenski standard je istoveten z: EN 16679:2014

ICS:

11.020	Medicinske vede in zdravstvenovarstveni pripomočki na splošno	Medical sciences and health care facilities in general
55.020	Pakiranje in distribucija blaga na splošno	Packaging and distribution of goods in general

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EUROPEAN STANDARD

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English Version

Packaging - Tamper verification features for medicinal product packaging

Emballage - Témoins d'effraction pour emballages de médicaments

Verpackung - Merkmale zur Überprüfung von Manipulationen an Arzneimittelverpackungen

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

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Foreword

This document (EN 16679:2014) has been prepared by Technical Committee CEN/TC 261 “Packaging”, 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of an identical text or by endorsement, at the latest by June 2015, and conflicting national standards shall be withdrawn at the latest by June 2015.

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

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Introduction

Directive 2011/62/EU [1], commonly referred to as the “Falsified Medicines Directive” (FMD), amending Directive 2001/83/EC [2], requires safety features for certain medicinal products to provide verification of the “authenticity and identification of individual packs”, and “a device allowing verification of whether the outer packaging has been tampered with”.

Directives are implemented into Member States' national legislation. This document is primarily aimed at supporting the implementation of tamper verification features to packaging for medicinal products in the European Union (EU) and European Economic Area (EEA).

1 Scope

This European Standard specifies requirements and provides guidance for the application, use and check of tamper verification features to the packaging of medicinal products.

NOTE The packaging of medicinal products placed on the market and incorporating tamper verification features in accordance with this European Standard meets the requirements of Directive 2001/83/EC as amended by Directive 2011/62/EU. Article 54(o) of the Directive stipulates, that on the outer packaging of certain medicinal products or, where there is no outer packaging, on the immediate packaging shall appear, among others, “a device allowing verification of whether the outer packaging has been tampered with”.

The principles in this European Standard can be applied in other countries and sectors, as appropriate.

2 Terms and definitions

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

2.1
dispensing person
person authorized or entitled to supply medicinal products to the public

2.2
Falsified Medicines Directive
FMD
Directive 2011/62/EU

2.3
finished product
authorized medicinal product which has undergone all stages of production including packaging in its final container as it is dispensed, sold or otherwise supplied

2.4
immediate packaging
primary packaging
container or other form of packaging immediately in contact with the medicinal product

Note 1 to entry: The term immediate packaging, also known as primary packaging, has been chosen in the context of this European Standard because it is contained in Directive 2001/83/EC.

2.5
manufacturing authorization holder
natural or legal person or entity that is authorized for total or partial manufacture, and/or for the various processes of dividing up, packaging or presentation (in accordance with Directive 2001/83/EC, Article 40(2)

Note 1 to entry: This includes replacement of safety and tamper verification features (in accordance with Directive 2001/83/EC, Article 47a(1)(b) as amended by Directive 2011/62/EU).

2.6
marketing authorization holder
natural or legal person or entity responsible for placing the medicinal product on the market

2.7
outer packaging
secondary packaging
packaging into which the immediate packaging is placed as it is dispensed or otherwise supplied

Note 1 to entry: The term outer packaging, also known as secondary packaging, has been chosen in the context of this standard because it is contained in Directive 2001/83/EC.

2.8
tampering
unauthorized attempt to open the packaging

2.9
tamper verification feature
characteristic(s) allowing verification of whether the outer packaging of medicinal products or, where there is no outer packaging, the immediate packaging has been opened or tampered with

Note 1 to entry: Tamper verification “features” may be referred to as “devices”, see Directive 2001/83/EC, Article 54(o) as amended by Directive 2011/62/EU.

2.10
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

[SOURCE: EN ISO 9000:2005, 3.8.4]

3 General requirements

3.1 Tamper verification features

Tamper verification features shall be applied to packaging of certain medicinal products as required in Directive 2001/83/EC as amended by Directive 2011/62/EU.

3.2 Purpose of tamper verification features

Tamper verification features should provide an indication that the outer packaging of a finished product has been opened or tampered with (i.e. indicating a possible adulteration or entry of falsified medicinal products into the legitimate supply chain). Tamper verification features limit the ability to replace the contents of genuine packs.

Tamper verification features are only one element of the safety features against falsification of the FMD and will not by themselves prevent falsification of medicinal products.

3.3 Application and use of tamper verification features

The application of tamper verification features shall not compromise the readability of statutory information. The statutory text on the packaging should remain readable after opening the pack.

Applying tamper verification features may increase the physical strength needed to open the packaging.

3.4 Check of tamper verification features

The tamper verification feature should enable a visual check for its presence and any evidence of tampering (see 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9 and 4.10 for details).

The immediate packaging of medicinal products may also provide tamper verification. This serves a different purpose, most significantly to prevent interference with the medicinal product itself and does not meet the tamper verification requirements of Directive 2001/83/EC as amended by Directive 2011/62/EU. However it also provides another level of protection against tampering but only in combination with additional measures as described.

Wholesalers, dispensing persons and other authorized persons may need access to information on the tamper verification features employed on particular products.

NOTE Other authorized persons include holders of a manufacturing authorization or customs authorities.

4 Categories of tamper verification features

4.1 General

Tamper verification technologies applied on the packaging are under constant evolution. Nine broad categories of tamper verification features are described in this European Standard (see 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9 and 4.10). Other tamper verification features may exist or be developed and shall meet the requirements of this European Standard as appropriate. The illustrations in Clause 4 are non-exhaustive.

Annex A provides additional information on tamper verification features as listed in 4.2 to 4.10.

If there is no outer packaging, the immediate packaging (e.g. bottles and tubes) should be equipped with a tamper verification feature in accordance with 4.4 to 4.10.

Tamper verification features shall meet the requirements of Clause 3.

The marketing authorization holder shall decide (if legally required) on appropriate tamper verification feature(s) out of the following (see 4.2 to 4.11).

This choice may be based on an assessment that takes into account a number of factors including technical feasibility, appropriateness, effectiveness, other safety features used on the product, and overall cost.

4.2 Folding boxes closed with glue

4.2.1 Description

A glue, e.g. hot melt, polyurethane, dispersion or other glues, or a combination of glues is applied to close the folding box. These boxes may incorporate perforations to facilitate the opening of the pack.

4.2.2 Criteria of tamper verification

Folding boxes closed with glue shall be cut or torn to gain access to the product. The box cannot be opened without visual tear-off/ripping-off of the carton board surface and/or other parts of the folding box.

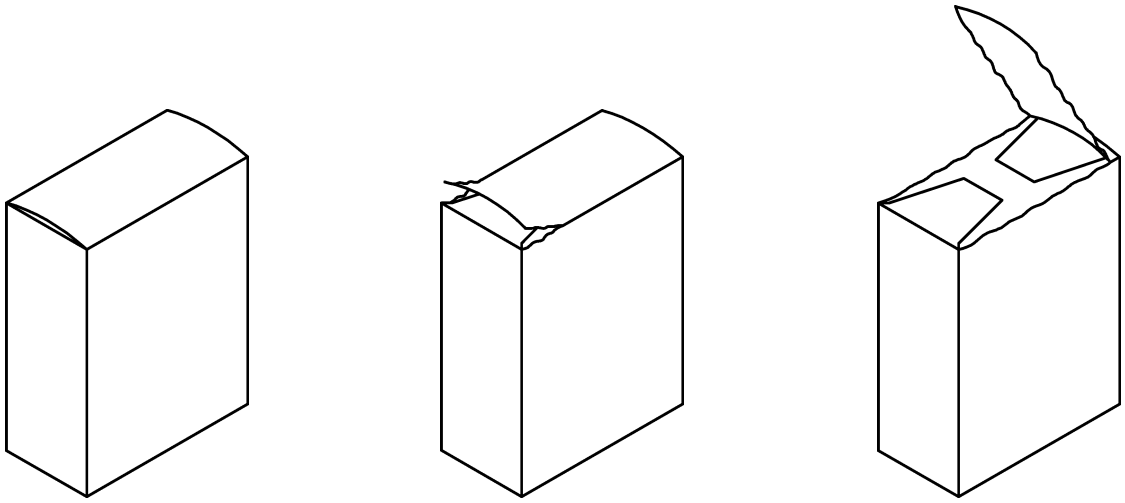
4.2.3 Verification

First time opening of the folding box leads to visible damage of the folding box integrity, for example (see Figure 1 and Figure 2):

— visible damage of one or more of the flaps (see Figure 1 b) and Figure 1 c));

— visible damage of perforations (see Figure 2 b) and Figure 2 c));

— visible damage of other parts of the folding box.

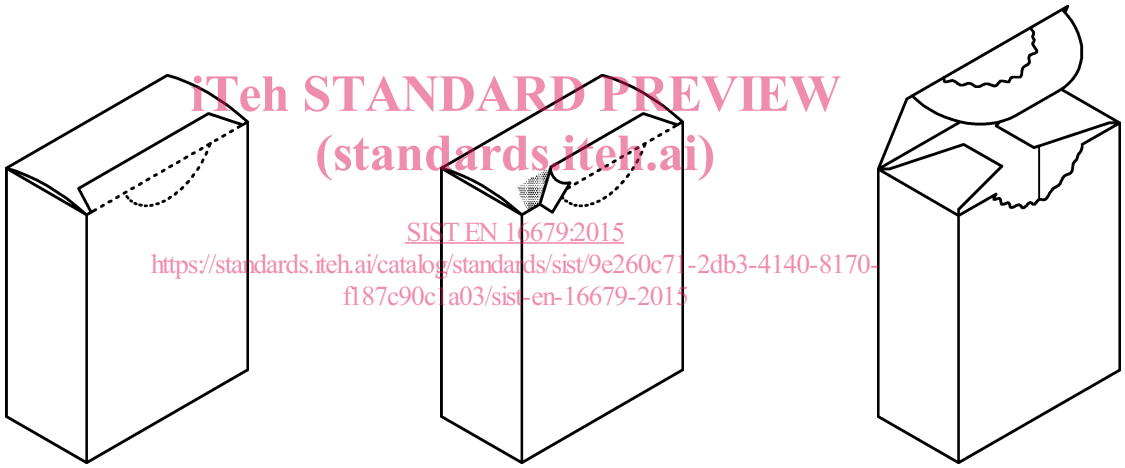


a) Original condition

b) Where the opening of the box has been tried

c) Opened

Figure 1 — Example of a folding box closed with glue



a) Original condition

b) Where the opening of the box has been tried

c) Opened

Figure 2 — Example of a folding box with perforations closed with glue

4.3 Specially constructed folding boxes

4.3.1 Description

The flaps and the body of the folding box are constructed in such a way that the feature is activated/enabled by inserting the flaps by the manufacturer to close the folding box. First time opening leads to a visible, irreversible change of the folding box appearance in such way, that parts of the flaps or of the folding box are damaged.

4.3.2 Criteria of tamper verification

The closure is set up in such a way that, the first time the box is opened, parts of the flaps or of the folding box are ripped off and/or are torn.