SIST

SLOVENSKI STANDARD
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Embalaža - Značilnosti preverjanja nedovoljenega poseganja v embalažo za zdravila (ISO 21976:2018)

Packaging - Tamper verification features for medicinal product packaging (ISO 21976:2018)

Verpackung - Merkmale zur Überprüfung von Manipulationen an Arzneimittelverpackungen (ISO 21976:2018)

Emballage - Témoins d'effraction pour emballages de médicaments (ISO 21976:2018)

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Packaging — Tamper verification features for medicinal product packaging

Emballage — Témoins d'effraction pour emballages de médicaments

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 122, *Packaging.*

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Requirements for tamper verification features on medicinal product packaging are emerging and expanding globally to reduce risk and improve patient safety.

This document is to support the harmonization and implementation of tamper verification features to the packaging of medicinal products worldwide.

The knowledge and experience gained in EN 16679:2014 has been used for developing this document. The background for the creation of a European Standard for tamper verification features for medicinal product packaging (EN 16679) was the European Directive 2001/83/EC[6], as amended by Directive 2011/62/EU[7], the latter commonly referred to as the "Falsified Medicines Directive" (FMD).

The packaging of medicinal products placed on the market and incorporating tamper verification features in accordance with this document meets, as an example but not limited to, the requirements of Directive 2001/83/EC[6] as amended by Directive 2011/62/EU[7]. 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 must appear, among others, "a device allowing verification of whether the outer packaging has been tampered with".

Packaging — Tamper verification features for medicinal product packaging

1 Scope

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

The principles in this document can be applied in other sectors, as appropriate.

2 Normative references

There are no normative references in this document.

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

— IEC Electropedia: available at http://www.electropedia.org/

3.1
falsified medicinal product
medicinal products (3.6) that deliberately/fraudulently misrepresent their identity, composition or source

[SOURCE: WHO, Definitions of Substandard and Falsified (SF) Medical Products, 2017[17]]

3.2
finished product
authorized *medicinal product* (3.6) which has undergone all stages of production including packaging in its final container as it is dispensed, sold or otherwise supplied

3.3
immediate packaging
primary packaging
container or other form of packaging directly in contact with the *medicinal product* (3.6)

3.4
manufacturing authorization holder
natural or legal person or entity that is authorized for total or partial manufacture

Note 1 to entry: This includes replacement of safety and *tamper verification features* (3.9) (in accordance with Directive 2001/83/EC[6], Article 47a(1)(b) as amended by Directive 2011/62/EU[7]).

3.5
marketing authorization holder
natural or legal person or entity responsible for placing the *medicinal product* (3.6) on the market

3.6
medicinal product
substance or combination of substances that may be administered to human beings (or animals) for treating or preventing disease, with the aim/purpose to making a medical diagnosis or to restore, correct or modify physiological functions

[SOURCE: ISO 11615:2017, 3.1.50, modified — "Pharmaceutical product" has been replaced by "substance" in the definition. The Notes to entry have been deleted.]

3.7
outer packaging
secondary packaging
packaging designed to contain one or more primary packagings together with any protective materials where required

[SOURCE: ISO 21067-1:2016, 2.2.4, modified — "Outer packaging" has been added as an admitted term.]

3.8
tampering
unauthorized attempt to open, manipulate or re-use the packaging or elements of it

3.9
tamper verification feature
characteristic(s) allowing *verification* (3.10) of whether the *outer packaging* (3.7) of *medicinal products* (3.6) 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 "anti-tampering devices".

3.10
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

[SOURCE: ISO 9000:2015, 3.8.12, modified — The Notes to entry have been deleted.]

4 General requirements

4.1 Tamper verification features

Tamper verification features shall be applied to packaging of medicinal products as required, or may be applied for other situations.

4.2 Purpose of tamper verification features

Tamper verification features should provide an indication that the packaging of a finished product has been opened or tampered with, i.e. indicating a possible adulteration or unauthorized attempt to open the packaging 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 possible safety features against falsification and do not, by themselves, prevent falsification of medicinal products.

4.3 Application and use of tamper verification features

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

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

