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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/20

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

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

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European foreword

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The text of ISO 21976:2018 has been approved by CEN as EN ISO 21976:2020 without any modification.

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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.

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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.

ISO 21976:2018(E)

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.

koniec náhľadu – text ďalej pokračuje v platenej verzii STN