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Packaging - Tamper verification features for medicinal product packaging

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

This European Standard was approved by CEN on 8 November 2014.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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of an identical text or by endorsement, at the latest by June 2015, and conflicting national standards shall be withdrawn at the latest by June 2015.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.