Irish Standard
I.S. EN 16679:2014

Packaging - Tamper verification features for medicinal product packaging

I.S. EN 16679:2014

Incorporating amendments/corrigenda/National Annexes issued since publication:

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NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

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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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EUROPÄISCHES KOMITEE FÜR NORMUNG

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of an identical text or by endorsement, at the latest by June 2015, and conflicting national standards shall be withdrawn at the latest by June 2015.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

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.