

BS EN 16679:2014



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Packaging — Tamper verification features for medicinal product packaging

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The UK participation in its preparation was entrusted to Technical Committee PKW/0/-/5, Packaging - Product Identification (Braille).

A list of organizations represented on this committee can be obtained on request to its secretary.

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of an identical text or by endorsement, at the latest by June 2015, and conflicting national standards shall be withdrawn at the latest by June 2015.

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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).