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# Foreword

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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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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