

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General requirements	2
4.1 Tamper verification features	2
4.2 Purpose of tamper verification features	2
4.3 Application and use of tamper verification features	2
4.4 Check of tamper verification features	3
5 Categories of tamper verification features	3
5.1 General	3
5.2 Folding boxes closed with glue	3
5.2.1 Description	3
5.2.2 Criteria of tamper verification	3
5.2.3 Verification	3
5.3 Specially constructed folding boxes	4
5.3.1 Description	4
5.3.2 Criteria of tamper verification	5
5.3.3 Verification	5
5.4 Sealing labels and tapes	5
5.4.1 Description	5
5.4.2 Criteria of tamper verification	6
5.4.3 Verification	6
5.5 Film wrappers	7
5.5.1 Description	7
5.5.2 Criteria of tamper verification	7
5.5.3 Verification	7
5.6 Sleeves	7
5.6.1 Description	7
5.6.2 Criteria of tamper verification	7
5.6.3 Verification	7
5.7 Breakable or tear-away closure	8
5.7.1 Description	8
5.7.2 Criteria of tamper verification	8
5.7.3 Verification	8
5.8 Container inner seal or membrane	9
5.8.1 Description	9
5.8.2 Criteria of tamper verification	9
5.8.3 Verification	10
5.9 Display blister pack	10
5.9.1 Description	10
5.9.2 Criteria of tamper verification	10
5.9.3 Verification	11
5.10 Flexible packaging	11
5.10.1 Description	11
5.10.2 Criteria of tamper verification	11
5.10.3 Verification	11
5.11 Blow-fill-and-seal-container (BFS)	12
5.11.1 Description	12
5.11.2 Criteria of tamper verification	12
5.11.3 Verification	12

5.12 New and emerging technologies	13
Annex A (informative) Additional information regarding tamper verification features.....	14
Bibliography	15

QUESTO DOCUMENTO È UNA PREVIEW. RIPRODUZIONE VIETATA

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.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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