

# INTERNATIONAL STANDARD

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**13127**

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## **Packaging — Child resistant packaging — Mechanical test methods for reclosable child resistant packaging systems**

*Emballages — Emballages à l'épreuve des enfants — Méthodes  
d'essais mécaniques pour systèmes d'emballage refermables à  
l'épreuve des enfants*



Reference number  
ISO 13127:2012(E)

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<b>Contents</b>	<b>Page</b>
<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 General requirements</b> .....	<b>2</b>
<b>4.1 Rationale</b> .....	<b>2</b>
<b>4.2 Reference data</b> .....	<b>2</b>
<b>4.3 Package modifications</b> .....	<b>2</b>
<b>4.4 Testing facilities</b> .....	<b>4</b>
<b>4.5 Test methods</b> .....	<b>5</b>
<b>4.6 Test method selection</b> .....	<b>5</b>
<b>4.7 Component verification</b> .....	<b>5</b>
<b>5 Samples</b> .....	<b>5</b>
<b>5.1 Sample selection</b> .....	<b>5</b>
<b>5.2 Sample preparation</b> .....	<b>5</b>
<b>6 Testing</b> .....	<b>5</b>
<b>6.1 Applicability of tests</b> .....	<b>5</b>
<b>6.2 Specific tests</b> .....	<b>6</b>
<b>6.3 Assessment of test results</b> .....	<b>6</b>
<b>7 Test report</b> .....	<b>6</b>
<b>7.1 General</b> .....	<b>6</b>
<b>7.2 Test facility (name and address)</b> .....	<b>6</b>
<b>7.3 Applicant (name and address)</b> .....	<b>6</b>
<b>7.4 Report number</b> .....	<b>7</b>
<b>7.5 Date</b> .....	<b>7</b>
<b>7.6 Manufacturer</b> .....	<b>7</b>
<b>7.7 Packaging description</b> .....	<b>7</b>
<b>7.8 References</b> .....	<b>7</b>
<b>7.9 Test description and results</b> .....	<b>7</b>
<b>7.10 Signature</b> .....	<b>7</b>
<b>Annex A (normative) Torque release test</b> .....	<b>8</b>
<b>Annex B (normative) Squeeze test</b> .....	<b>9</b>
<b>Annex C (normative) Non-squeeze torque test</b> .....	<b>10</b>
<b>Annex D (normative) Press down and turn engagement test</b> .....	<b>11</b>
<b>Annex E (normative) Push and turn test</b> .....	<b>12</b>
<b>Annex F (normative) Reverse ratchet torque test</b> .....	<b>13</b>
<b>Annex G (normative) Disassembly test</b> .....	<b>14</b>
<b>Annex H (normative) Rotational torque test</b> .....	<b>17</b>
<b>Annex I (normative) Push-off force</b> .....	<b>18</b>
<b>Annex J (normative) Application force</b> .....	<b>19</b>
<b>Bibliography</b> .....	<b>20</b>

## ISO 13127:2012(E)

### 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 13127 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 261, *Packaging*, in collaboration with ISO Technical Committee ISO/TC 122, *Packaging*, Subcommittee SC 3, *Performance requirements and tests for means of packaging, packages and unit loads*, in accordance with the agreement on technical cooperation between ISO and CEN (Vienna Agreement).

## Introduction

A significant number of suspected cases of ingestion by children of products used about the home is reported to the medical profession each year. Most are not serious and those that are associated with more serious side effects involve products known to be hazardous, e.g. certain medicinal products, liquid fuels and solvents, strongly acid or alkaline preparations and some garden products. Most commonly used household detergents, cleaning agents and maintenance and care products are not known to have caused injury. However, whether ingestion (actual or suspected) causes injuries or not, such incidents can have traumatic effects on both the child and its parents.

The use of potentially hazardous agents in certain products is necessary to achieve effectiveness; consequently steps have to be taken to limit the occurrence of accidents. One approach has been to try to increase general awareness of hazards associated with various products. Nevertheless, proper labelling and information by the manufacturer is important for the safe use of products in the home.

Another approach has been the use of child resistant packaging to put a physical barrier between the child and the hazardous product. Such packaging should only be used for products as mentioned above since, if used in other circumstances, it could lead to confusion among consumers. It is important to recognize that it is unrealistic to expect that any functional packaging can be totally impossible for a child to open and this type of packaging cannot be a substitute for normal safety precautions. The packaging functions as a last defence if other barriers separating children and hazardous products have failed. Hence, the overall responsibility rests with the parents or other responsible adults.

The aim of this International Standard is to establish mechanical test methods to safeguard child resistance properties of the packaging system.

According to ISO 8317, the panel test is intended for initial type approval but it does not sufficiently cover change management.

NOTE Change management covers, but is not limited to, for example, change of supplier, packaging material, component manufacturing site, material brand or scale up.

Those changes need to be assessed using risk management procedures. Mechanical test methods deliver scientific data which introduce a more scientific means of ensuring compliance with the originally type tested package. The test results are essential for an appropriate risk assessment.

The object of this International Standard is to permit the comparison, by mechanical testing, of the physical parameters of the packaging system under test with those of the individual units tested for certification purposes. It is the responsibility of the component manufacturer to provide access to test methods and test data to the customer.



# Packaging — Child resistant packaging — Mechanical test methods for reclosable child resistant packaging systems

## 1 Scope

This International Standard specifies test methods for mechanical testing of reclosable child resistant packaging. The data generated by these mechanical test methods are suitable for comparing child resistant characteristics of related reclosable packaging systems.

This International Standard is not intended for routine quality assurance purposes.

NOTE The use of children and adults for testing in accordance with ISO 8317 is an essential feature of that standard.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8317, *Child-resistant packaging — Requirements and testing procedures for reclosable packages*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8317 and the following apply.

### 3.1

#### **mechanical testing**

documented and reproducible methods intended to measure the resistance of the relevant features of a child resistant packaging system

### 3.2

#### **essential characteristics**

those elements of the container/closure system that are critical for maintaining the child resistant functionality

NOTE See 4.3 for examples of essential characteristics.

### 3.3

#### **thread system**

child resistant packaging system having a combination of container and closure that is reliant on having compatible threads in order to maintain the child resistance functions and sealing integrity

### 3.4

#### **squeeze and turn system**

child resistant packaging system which requires the user to squeeze the closure at designated points while simultaneously applying a torque to unscrew the closure from the container

### 3.5

#### **push and turn system**

#### **press and turn system**

child resistant packaging system which requires the user to apply a downward force while simultaneously applying a torque to unscrew the closure from the container

## ISO 13127:2012(E)

**3.6**  
**snap-cap system**  
**align and lift system**  
child resistant packaging system which requires the user to align marks on the container and closure before pushing off the closure

**3.7**  
**liner**  
medium used to form a seal between a closure and a container

**3.8**  
**original specification**  
full description of all components of the test specimens, including reference to number and issue of drawings, dimensions, tolerances and material specification for all components

NOTE Components include, but are not limited to, closures, liners or containers.

**3.9**  
**reference data**  
data generated from type-approved child resistant packages using the testing methods specific to the packaging type as given in this International Standard

NOTE Reference data provide the link between packages tested and found to be compliant with ISO 8317 and the packages to be tested according to this International Standard.

## 4 General requirements

### 4.1 Rationale

This International Standard is intended to be used to generate mechanical test data from reclosable child resistant packaging systems. These data may be used for the verification of equivalency of a child resistant packaging system to a type-approved package (e.g. in the course of change management) and aims to avoid unnecessary panel tests.

### 4.2 Reference data

Reference data shall be generated from type-approved packages using the testing methods specific to the packaging type as given in Clause 6. Reference data should preferably be generated on the same package lot(s) as used for type approval testing to ISO 8317. Where this is not possible, reference data may be generated on an alternative lot, or lots, of the package, providing that the package lot is identical in design, construction and specification to the type-approved package.

The identified test methods used to generate data from packages submitted for testing to ISO 8317, or from packages fulfilling the specification, shall be used to set the test parameters for the range of packaging covered by the original certification. Specifications with appropriate tolerances for the specific packaging shall be defined when generating reference data.

### 4.3 Package modifications

ISO 8317 establishes that mechanical testing may be used to confirm the continued compliance of child resistant packages, subject to minor changes to the package that was type-approved to ISO 8317.

NOTE Changes to a type-approved package that would result in the package being outside the criteria or dimensions of a series of similar packages, require panel testing according to ISO 8317 to confirm compliance as a child resistant package.

The suitability and ability of mechanical testing to assess the impact of changes to a type-approved child resistant package will vary according to the nature of the proposed changes. To decide upon this, for each proposed change, a risk assessment shall be conducted to identify the potential impacts of the proposed



change, and identify and assess the ability of the selected mechanical test methods to suitably measure those impacts. The risk assessment and the rationale for the selected test methods shall be recorded.

Only where the impact of any change on child resistance performance can be reliably measured and quantified by mechanical testing may mechanical testing alone be used to assess the continued compliance as a child resistant package. In all other circumstances, child and adult panel testing according to ISO 8317 shall be conducted.

Changes affecting the essential characteristics shall be thoroughly evaluated in the course of the risk assessment. The following elements are considered as essential characteristics of the container/closure system and are important to maintain the child resistant functionality:

a) Container

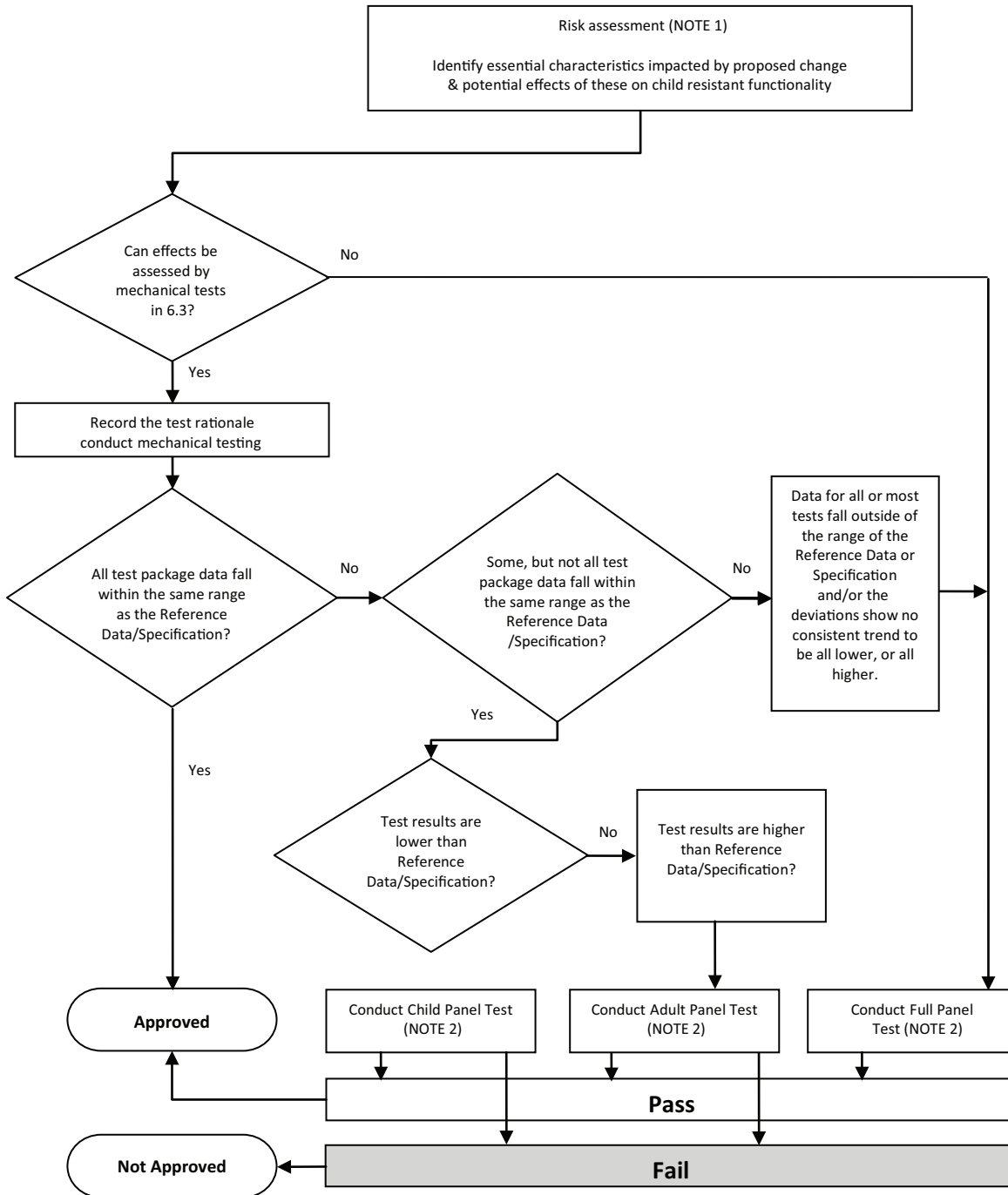
- critical dimensions;
- material: glass, metal, different polymers, etc.;
- shape: round, square, rectangular, oval, etc.;
- handling: handle position, handle design, etc.;
- thread: form, position;
- neck: position, orientation, design, etc.;
- rigidity.

b) Closure

- critical dimensions;
- material: metal, different polymers, etc.;
- shape: round, square, rectangular, oval, etc.;
- handling: external gripping feature;
- thread: form, position;
- child resistant system: push down and turn, squeeze and turn, etc.;
- sealing feature: wad-liner, plug, etc.

The decision making process for the application of mechanical testing of minor changes to a type-approved package is illustrated in Figure 1.

NOTE The mechanical test methods described in this International Standard are only capable of measuring unidirectional (vertical and lateral) compression and tension forces, and rotational torque; they cannot measure or quantify frictional or grip forces, for example, between a hand(s) and a package. Changes to a type-approved package that have the potential to impact the hand grip of a child or adult on the package cannot therefore be assessed by methods described in this International Standard.



NOTE 1 The use of suitable risk assessment methodology should be considered (e.g. IEC ISO 31010).

NOTE 2 Or reject modification.

**Figure 1 — Decision flowchart for the use of mechanical testing of modifications to a type-approved package**

#### 4.4 Testing facilities

Tests shall be carried out at a testing facility capable of meeting the operational provisions specified in ISO/IEC 17025.

NOTE This does not imply a requirement for accreditation but, if appropriate, such external approval may be obtained from either a national accreditation body or from the competent authority.

## 4.5 Test methods

A number of mechanical test methods for different types of packaging systems are given in Annexes A to J.

Commercially available test equipment with appropriate jigs and fixtures for the packaging under test may be used where appropriate.

## 4.6 Test method selection

Specific test methods, as given in 6.2, shall be chosen depending on the packaging type to be tested. Additional test methods identified by the risk assessment can also be applied after validation. Their use and the rationale for their use shall be recorded in the test report.

## 4.7 Component verification

It is the responsibility of the person(s) carrying out the mechanical test to ensure that the components match the specification and that all functional parts of the system are present.

# 5 Samples

## 5.1 Sample selection

Child resistant packages submitted for mechanical testing shall be new and unfilled. Some safety features will require the testing of individual components. Where the package depends for its child resistant properties on the interaction between two or more components (e.g. lugs on the container engaging with features on the cap) the system shall always be tested as a whole.

## 5.2 Sample preparation

A minimum of 10 samples per test shall be used.

Packages which incorporate an exterior and/or interior tamper-evident seal in addition to being child resistant shall have the seal broken.

Containers and closures shall be assembled and closed according to their specification. Where torque is required to apply the closure, the specified application torque shall be that recorded in the ISO 8317 test report for the certified package.

A sample of the test package shall be opened and properly reclosed to check its functionality. This sample shall then be discarded.

The assembled containers and closures shall be stored for 72 h at  $(23 \pm 2)^{\circ}\text{C}$  and  $(50 \pm 5)\%$  RH prior to conducting tests. This is to allow materials (e.g. closure or liner) to take "a set".

Testing shall be conducted immediately after conditioning of the packages.

NOTE It is recommended that assembly should not be carried out less than 24h after moulding to allow dimensional stability to be achieved.

# 6 Testing

## 6.1 Applicability of tests

For generation of reference data, the child resistant package shall undergo the specific tests given in 6.2. For modified packages, the system shall be tested according to the relevant tests in 6.2 as identified by the risk assessment described in 4.3. Additional tests may be applied if required.