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## Dentistry — Brackets and tubes for use in orthodontics

*Médecine bucco-dentaire — Consoles et tubes utilisés en orthodontie*





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## 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](http://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](http://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](http://www.iso.org/iso/foreword.html).

ISO 27020 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This second edition cancels and replaces the first edition ISO 27020:2010, which has been technically revised. The main changes compared to the previous edition are as follows:

- the inclusion of a new corrosion test.

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](http://www.iso.org/members.html).

## Introduction

This document has been developed as a result of the difficulty often encountered by clinicians to make meaningful comparisons between brackets and tubes using the information currently available from manufacturers and suppliers.



# Dentistry — Brackets and tubes for use in orthodontics

## 1 Scope

This document specifies requirements and test methods to compare the functional dimensions of orthodontic brackets and tubes and their chemical ion release, as well as packaging and labelling information.

This document is applicable to brackets and tubes for use in fixed orthodontic appliances.

This document does not specify specific qualitative and quantitative requirements for freedom from biological hazards; which are covered in ISO 10993-1 and ISO 7405.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1942, *Dentistry — Vocabulary*

ISO 10271:2011, *Dentistry — Corrosion test methods for metallic materials*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following 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

#### angle of torque

$\theta$

occlusal-gingival angle formed between the intersection of the line perpendicular to the tangent to the tooth side surface of the base and the line bisecting the *slot* (3.12) in the occlusal-gingival direction, when viewed along the mesial-distal long-axis of the *slot* (3.12)

Note 1 to entry: If the angle is oriented toward the occlusal (gingival), it is designated as positive (negative).

Note 2 to entry: See [Figure 1](#).

### 3.2

#### angulation

$\alpha$

angle between the line perpendicular to the mesial-distal long-axis of the slot and the central occlusal-gingival axis of the *bracket/tube* (3.9), when viewed from the buccal/labial

Note 1 to entry: The angulation is positive (negative) when the gingival part of the central occlusal-gingival axis is inclined toward the distal (mesial) relative to the line perpendicular to the mesial-distal long-axis of the slot.

Note 2 to entry: See [Figure 2](#).

### 3.3

#### **archwire**

wire that is formed approximately to the shape of the dental arch

### 3.4

#### **auxiliary slot**

additional opening in the *bracket* or *tube* (3.9) for insertion of auxiliary elements

### 3.5

#### **auxiliary slot dimensions**

diameter/cross-sectional dimensions of the largest wire that passes through an *auxiliary slot* (3.4)

### 3.6

#### **band**

structural annular component affixed to the outer circumference of the crown of a tooth and to which a *bracket* or *tube* (3.9) can be attached

### 3.7

#### **base**

part of the *bracket* or the *tube* (3.9) that is attached to the enamel or *band* (3.6)

### 3.8

#### **descriptor**

code to identify the nominal *slot* (3.12) height in thousandths of an inch without unit designation, in accordance with accepted orthodontic practice (e.g. 18 or 22)

### 3.9

#### **bracket**

#### **tube**

structural unit attached to a *band* (3.6) or *base* (3.7) that is capable of retaining an *archwire* (3.3)

### 3.10

#### **in-out**

distance between the floor of the *slot* (3.12) and the tooth side surface of the *base* (3.7)/*band* (3.6)

#### **3.10.1**

##### **bracket in-out**

$l_i$

distance between the floor of the *slot* (3.12) and the tooth side surface of the *base* (3.7)/*band* (3.6) along the intersection of the plane perpendicular to mesial-distal long-axis of the *slot* (3.12) in the centre of the *bracket* (3.9) *slot* (3.12) and the plane bisecting the *slot* (3.12) in the occlusal-lingual direction, when viewed along the mesial-distal long-axis of the *slot* (3.12)

Note 1 to entry: See Figure 3 a).

#### **3.10.2**

##### **tube in-out**

$l_i$

distance between the floor of the *slot* (3.12) and the tooth side surface of the *base* (3.7)/*band* (3.6), at the mesial end of the tube and in the midplane of the *slot* (3.12) in the occlusal-lingual direction;

Note 1 to entry: For tubes with a mesial chamfer, the in-out is the distance at the mesial end of the tube between that part of the floor of the slot in contact with the largest dimension of an archwire (round wire for a round tube and a rectangular wire for a rectangular tube) able to pass the entire tube, and the tooth side surface of the base in the midplane of the slot in the occlusal-lingual direction, when viewed from the lingual.

Note 2 to entry: See Figure 3 b).



**3.11****rotational offset** $\delta$ 

angle between a line parallel to the floor of the *slot* (3.12) and the line connecting the points of intersection of the lines along the mesial and distal end-faces of the *slot* (3.12) at the tooth side surface of the *base* (3.7), when viewed from the occlusal

Note 1 to entry: When the distal (mesial) part of the floor of the slot is furthest from the tooth it is known as a distal (mesial) offset.

Note 2 to entry: See [Figure 4](#).

**3.12****slot**

mesial-distal oriented opening in a *bracket* or *tube* (3.9) primarily to contain an *archwire* (3.3)

**3.13****slot depth** $d$ 

minimum buccal-lingual dimension of a rectangle where the projection of its buccal/labial side is tangent to the shorter side of the intended *slot* (3.12), when viewed along the mesial-distal axis of the *slot* (3.12)

Note 1 to entry: See [Figure 5](#).

**3.14****slot height** $h$ 

maximum occlusal-gingival dimension of a rectangle that is fully engaged in the *slot* (3.12), when viewed along the mesial-distal long-axis of the *slot* (3.12)

Note 1 to entry: See [Figure 5](#).

**3.15****slot length** $l_s$ 

smallest mesial-distal dimension of the *slot* (3.12) between the mesial and distal ends of the *slot* (3.12)

**4 Requirements****4.1 Hazardous elements**

For the purposes of this document, cadmium, beryllium, lead and nickel are designated to be hazardous elements, and the manufacturer shall state the concentrations as a mass fraction expressed as a percentage.

## 4.2 Dimensions and angles

**4.2.1** The following dimensions shall be recorded to the nearest 0,01 mm. When determined in accordance with [5.1](#), the following dimensions of the product shall comply with the ranges stated by the manufacturer:

- a) in-out  $l_i$
- b) slot depth  $d$
- c) slot height  $h$
- d) slot length  $l_s$
- e) dimensions of each auxiliary slot.

**4.2.2** The following angles shall be recorded to the nearest 1°. When determined according to [5.1](#), the following angles of the product shall comply with the ranges stated by the manufacturer:

- a) angle of torque  $\theta$
- b) angulation  $\alpha$
- c) the rotational offset  $\delta$

## 4.3 Release

With metallic containing brackets, the static immersion corrosion tests release for each element found and the total ions shall be recorded as  $\mu\text{g}/20$  brackets/7 days to the nearest 10  $\mu\text{g}/20$  brackets/7 days, and with metallic containing tubes, the static immersion corrosion test release for each element found and the total ions shall be recorded as  $\mu\text{g}/8$  tubes/7 days to the nearest 10  $\mu\text{g}/8$  tubes/7 days. When determined according to [5.2](#), the static immersion corrosion release of the product shall comply with the ranges stated by the manufacturer.

## 5 Test methods

All tests described in this document are type tests. Type tests shall be made on representative samples of the item being tested.

### 5.1 Dimensions

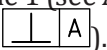
#### 5.1.1 Apparatus

Measurements shall be taken with callipers, micrometers, optical comparators, or other devices with an accuracy of 0,005 mm or 0,5°.


#### 5.1.2 Measurement procedures

##### 5.1.2.1 Angle of torque ([Figure 1](#))

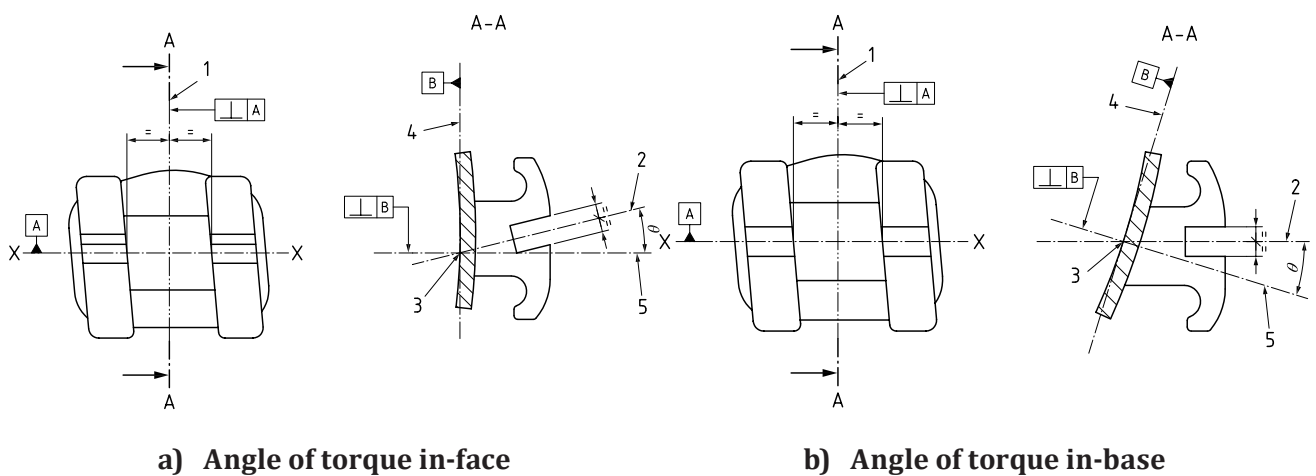
**5.1.2.1.1** When viewed from the labial/buccal, perform the following:

- a) Construct a line along the mesial-distal long-axis of the slot (X-axis).
- b) Construct plane 1 (see A-A in [Figure 1](#)) perpendicular to the X-axis in the centre of the slot (depicted by the symbol .

**5.1.2.1.2** When viewed in plane 1, perform the following in plane 1.

- Construct line 2 bisecting the slot in the occlusal-lingival direction.
- At the point of intersection of the tooth side surface of the base and line 2 (point 3 in [Figure 1](#)), construct line 4 tangent to the tooth side surface of the base.
- Construct line 5 perpendicular to line 4 (depicted by the symbol ) passing through point 3.
- Measure the angle of torque,  $\theta$ , between line 5 and line 2.

A suggested method is to view along the mesial-distal long-axis of the slot (X-axis) of the bracket or tube and place a convex radius template in plane 1 of the bracket or tube, against the tooth side surface of the base, thus constructing the tooth side surface of the base. Then construct lines 2, 4 and 5 as defined above.




#### Key

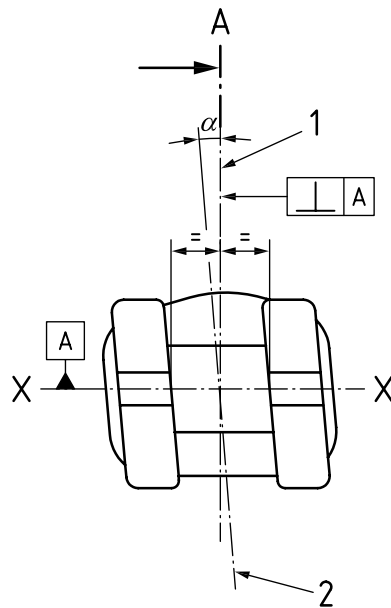
- X mesial-distal long-axis of the slot
- 1 plane perpendicular to the X-axis in the centre of the slot
- 2 line bisecting the slot in the occlusal-lingival direction
- 3 point of intersection of line 2 to the tooth side surface of the base
- 4 line tangent to the tooth side surface of the base passing through point 3
- 5 line perpendicular to line 4 passing through point 3
- $\theta$  angle of torque

**Figure 1 — Angle of torque of the bracket or tube**

#### **5.1.2.2** Angulation (see [Figure 2](#))

Viewing from the labial/buccal, perform the following:

- Construct a line along the mesial-distal long-axis of the slot (X-axis).
- Construct line 1 (see A-A in [Figure 2](#)) perpendicular to the X-axis in the centre of the slot (depicted by the symbol )
- Construct line 2 along the central occlusal-lingival axis.
- Measure the angulation,  $\alpha$ , between line 1 and line 2.



**Key**

- X mesial-distal long-axis of the slot
- 1 line perpendicular to the X-axis in the centre of the slot
- 2 line along the central occlusal-lingual axis
- $\alpha$  angulation

**Figure 2 — Angulation of the bracket or tube**

**5.1.2.3 In-out** (see [Figure 3](#))

**5.1.2.3.1 Bracket in-out** [see [Figure 3 a](#)]

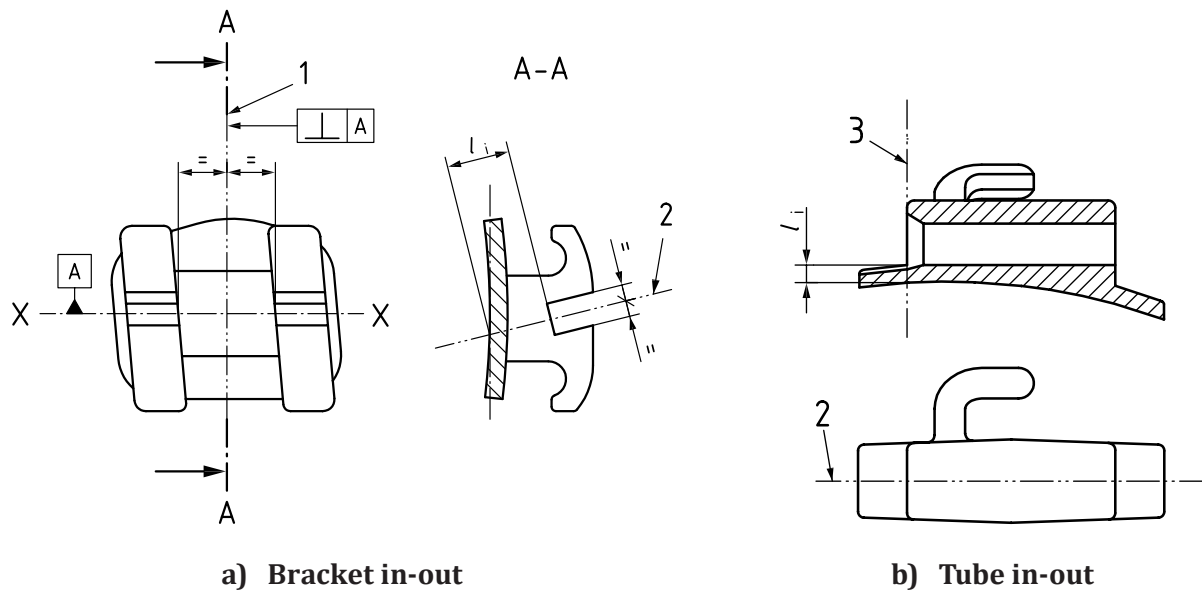
When viewed from the labial/buccal, perform the following:

- a) Construct a line along the mesial-distal long-axis of the slot (X-axis).
- b) Construct plane 1 [see A-A in [Figure 3 a](#)] perpendicular to the X-axis in the centre of the bracket slot (depicted by the symbol ).
- c) When viewed on plane 1, construct plane 2 bisecting the slot in the occlusal-lingual direction.
- d) In plane 1, measure the in-out distance  $l_i$  from the bottom of the slot to the intersection of plane 2 with the tooth side surface of the base.

**5.1.2.3.2 Tube in-out** [see [Figure 3 b](#)]

When viewed from the lingual, perform the following:

- a) Construct plane 2 bisecting the slot of the tube in the occlusal-lingual direction.
- b) When viewed on plane 2, construct plane 3 along the mesial end-face of the slot of the tube.
- c) Measure along the intersection of planes 2 and 3, then measure the in-out distance  $l_i$  from the bottom of the slot to the tooth side surface of the base.

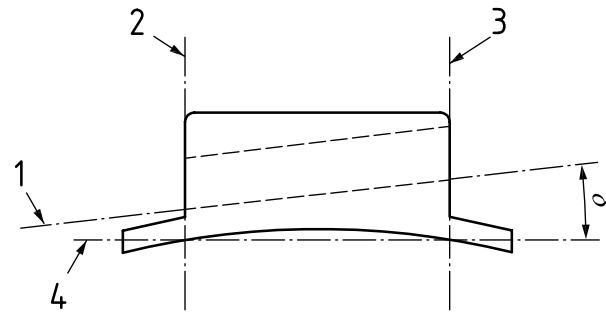
**Key**

- X mesial-distal long-axis of the slot
- 1 plane perpendicular to the X-axis in the centre of the bracket slot
- 2 plane bisecting the slot in the occlusal-lingual direction
- 3 plane perpendicular to an archwire that is fully engaged within the slot at the mesial end-face of the tube
- $l_i$  in-out

**Figure 3 — In-out****5.1.2.4 Rotational offset** (see [Figure 4](#))

When viewed from the occlusal, perform the following:

- a) Construct line 1 parallel to the direction of a straight section of wire that fills the slot.
- b) Construct lines 2 and 3 along the mesial and distal end-faces toward the base.
- c) Construct line 4 connecting the points of intersection of lines 2 and 3 with the tooth side surface of the base.
- d) Measure angle  $\delta$  between lines 1 and 4 as rotational offset.



**Key**

- 1 line parallel to the floor of the slot
- 2 line along the mesial end-faces of the slot
- 3 line along the distal end-faces of the slot
- 4 line connecting the points of intersection of lines 2 and 3 at the base
- $\delta$  rotational offset

**Figure 4 — Rotational offset — Occlusal view**

**5.1.2.5 Slot depth** (see [Figure 5](#))

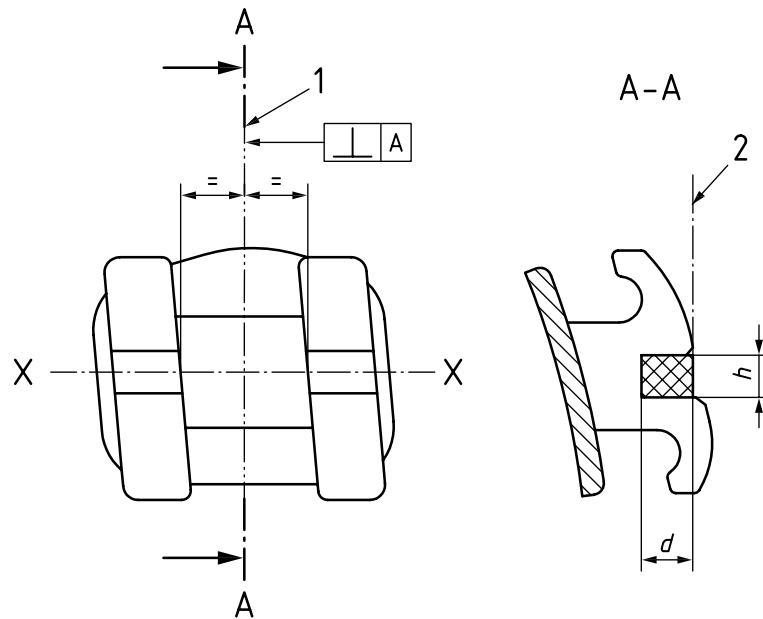
When viewed from the labial/buccal, perform the following:

- a) Construct a line along the mesial-distal long-axis of the slot (X-axis).
- b) Construct plane 1 (see A-A in [Figure 5](#)) perpendicular to the X-axis in the centre of the bracket slot (depicted by the symbol ).
- c) When viewed on plane 1, project line 2 tangent to the shorter side of the intended slot and the buccal/labial side of the rectangle.
- d) Measure the slot depth as the dimension  $d$ .

**5.1.2.6 Slot height** (see [Figure 5](#))

When viewed from the labial/buccal, perform the following:

- a) Construct a line along the mesial-distal long-axis of the slot (X-axis).
- b) Construct plane 1 (see A-A in [Figure 5](#)) perpendicular to the X-axis in the centre of the bracket slot (depicted by the symbol ).
- c) When viewed on plane 1, measure the maximum occlusal-gingival dimension  $h$ .

**Key**

- X mesial-distal long-axis of the slot
- 1 plane perpendicular to the X-axis in the centre of the bracket slot
- 2 projection of the buccal/labial side of a rectangle tangent to the shorter side of the intended slot
- $h$  slot height
- $d$  slot depth

**Figure 5 — Slot height and slot depth****5.2 Static immersion corrosion test method**

The test shall be performed per ISO 10271:2011 4.1 with the following modifications.

**5.2.1 Apparatus**

**5.2.1.1** Sealed containers, of borosilicate glass, with dimensions of approximately 100 mm inner diameter by 20 mm in height (See ISO 10271:2011, 4.1.4.1).

**5.2.1.2** Chemical analysis of ion concentration using apparatus capable of measuring concentrations in  $\mu\text{g/ml}$  (e.g. ICP-MS or equivalent; See ISO 10271:2011, 4.1.4.3).

**5.2.2 Samples**

**5.2.2.1** Sample shall be used in the as-received condition and shall be a case of orthodontic brackets, 5 to 5, maxillary and mandibular. Samples shall be sufficient to provide at least two identical sets (See ISO 10271:2011, 4.1.6.1.2).

**5.2.2.2** Sample shall be used in the as-received condition and shall be eight orthodontic tubes, on band and/or base, 1st and 2nd molar, maxillary and mandibular. Samples shall be sufficient to provide at least two identical sets (See ISO 10271:2011, 4.1.6.1.2).

### 5.2.3 Test procedure

**5.2.3.1** A set consisting of either: 20 brackets (one case) shall be placed in a single container, bonding surface down in contact with container and the brackets shall not touch each other (See ISO 10271:2011, 4.1.7).

**5.2.3.2** A set consisting of eight tubes shall be placed in a single container, bonding surface down or band horizontal in contact with container and the tubes shall not touch each other (See ISO 10271:2011, 4.1.7).

**5.2.3.3** Add the solution (see ISO 10271:2011, 4.1.5). to each container sufficient to produce a ratio of 50 ml of solution per 20 brackets or 8 tubes. The specimens shall be covered completely by the solution.

### 5.3 Treatment of results

The test results shall be within the manufacturer's specified range, [6.1 b\)](#) and [6.1 c\)](#), in order for the material to comply with the requirements.

## 6 Packaging and labelling information to be provided to the user

### 6.1 General requirements

The manufacturer shall make the following readily available in the catalogue, packaging insert, labelling or other readily accessible means:

- a) a declaration of chemical composition in which the range of composition of the material shall include all components present at concentrations of 0,1 % by mass fraction or greater, and the mass fractions of any hazardous elements as defined in [4.1](#)
- b) the range of each dimension, which shall be in accordance with [4.2](#);
- c) the static immersion corrosion released ions range for each element and the total ions, as  $\mu\text{g}/20$  brackets/7 days or  $\mu\text{g}/8$  tubes/7 days, which shall be in accordance with [4.3](#).

NOTE Additional information can be included at the discretion of the manufacturer or as required by legislation.

### 6.2 Packaging

Adequate containment and protection from contamination during transit and storage shall be provided in accordance with acceptable commercial practice.

### 6.3 Labelling

Each package shall be labelled with at least the following information:

- a) the name and address of the manufacturer or distributor, or both;
- b) the name or trade name of the bracket or tube;
- c) the descriptor of the bracket or tube;
- d) the lot number;
- e) the quantity of brackets or tubes within the package;
- f) a warning for products containing hazardous elements (where appropriate, this information should take the form of symbols);



g) the intended use.

## Bibliography

- [1] ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*
- [2] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*
- [3] ISO 15841, *Dentistry — Wires for use in orthodontics*



