

English Version

Dentistry - Shanks for rotary and oscillating  
instruments (ISO 1797:2017)

Médecine bucco-dentaire - Queues pour  
instruments rotatifs et oscillants (ISO 1797:2017)

Zahnheilkunde - Schäfte für rotierende und  
oszillierende Instrumente (ISO 1797:2017)

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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

## European foreword

This document (EN ISO 1797:2017) has been prepared by Technical Committee ISO/TC 106 “Dentistry” in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by November 2017, and conflicting national standards shall be withdrawn at the latest by November 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 1797-1:2011 , EN ISO 1797-2:1995 and EN ISO 1797-3:2013 .

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### Endorsement notice

The text of ISO 1797:2017 has been approved by CEN as EN ISO 1797:2017 without any modification.

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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)).

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For an explanation on 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 the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

This third edition cancels and replaces ISO 1797-1, ISO 1797-2, and ISO 1797-3, which have been technically revised with the following changes:

- a) combination of three material parts into one International Standard;
- b) reprocessing requirements for plastic shanks have been added;
- c) AQL-values have been deleted;
- d) quality control concept was moved to [Annex A](#).

# Dentistry — Shanks for rotary and oscillating instruments

## 1 Scope

This document specifies the requirements for dimensions and material properties of shanks used in dentistry for rotary or oscillating instruments. It describes the measurement methods for the verification of the requirements.

This document is not applicable to tips fixed to the handpiece with a screw, e.g. scaler tips.

Information about the location of marking is also given. [Annex A](#) on quality control is included in order to ensure a high quality level.

## 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 527-2 , *Plastics — Determination of tensile properties — Part 2: Test conditions for moulding and extrusion plastics*

ISO 1101 , *Geometrical product specifications (GPS) — Geometrical tolerancing — Tolerances of form, orientation, location and run-out*

ISO 1942 , *Dentistry — Vocabulary*

ISO 3274 , *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Nominal characteristics of contact (stylus) instruments*

ISO 4288 , *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Rules and procedures for the assessment of surface texture*

ISO 6507-1 , *Metallic materials — Vickers hardness test — Part 1: Test method*

ISO 8325 , *Dentistry — Test methods for rotary instruments*

ISO 14457 , *Dentistry — Handpieces and motors*

## 3 Terms, definitions and symbols

### 3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 , ISO 14457 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>



3.1.1  
handpiece

powered handheld device used to operate a rotary or *oscillating instrument* (3.1.3)

Note 1 to entry: This definition includes reciprocating instruments.

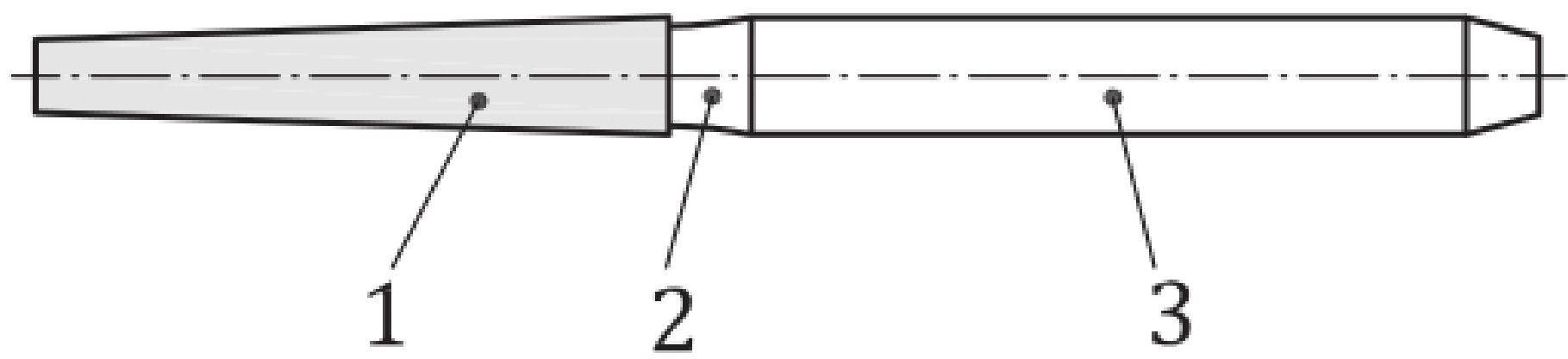
[SOURCE: ISO 14457:2012, 3.10, modified]

3.1.2  
instrument

tool used for rotary or oscillating movements, consisting of working part, neck (if applicable) and *shank* (3.1.5), which is constructed to fit into a *handpiece* (3.1.1)

Note 1 to entry: This includes continuous rotation or *oscillating instruments* (3.1.3).

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



- Key
- 1 working part
  - 2 neck
  - 3 shank

Figure 1 — Designation of instrument parts

3.1.3  
oscillating instrument

*instrument* (3.1.2) used with an alternate (cyclic) movement, including vibrating, consisting of a *shank* (3.1.5) and a working part used in a *handpiece* (3.1.1) for dental procedures

Note 1 to entry: All movements can be combined with axial movements.

3.1.4  
rotary instrument

*instrument* (3.1.2) used with a continuous rotation in a *handpiece* (3.1.1) consisting of a *shank* (3.1.5) and a working part used for dental procedures

3.1.5  
shank

part of the shaft of a rotary or *oscillating instrument* (3.1.3) used in dentistry which is designed to fit into the chuck of a *handpiece* (3.1.1) or a handpiece for laboratory use

3.1.6  
fitting length

length of the *shank* (3.1.5) that is contained within the chuck of a *handpiece* (3.1.1) or a handpiece for laboratory use

3.2 Symbols

- $d_1$  shank diameter
- $d_2$  diameter in the groove
- $d_3$  second distance for plastic shanks

$l_1$	fitting length
$l_2$	shoulder to end length
$l_3$	shoulder to groove length
$l_4$	width of groove
$l_5$	length of conical or rounded end
$R_a$	surface roughness
$s$	maximum distance from the circumference to the flat area
$\delta$	shank cylindricity

4 Classification

Shanks for rotary or oscillating instruments are classified into the following types, according to their diameters and designs:

- Type 1: RA (right angle), CA (contra angle): diameter 2,35 mm, with groove and flat area (see [Figure 2](#));
- Type 2: HP (handpiece): diameter 2,35 mm, cylindrical (see [Figure 3](#));
- Type 3: FG (friction grip): diameter 1,6 mm, cylindrical with conical or rounded end (see [Figure 4](#));
- Type 4: HP (handpiece): diameter 3 mm cylindrical (see [Figure 3](#)).

NOTE All movements can be combined with axial movements.

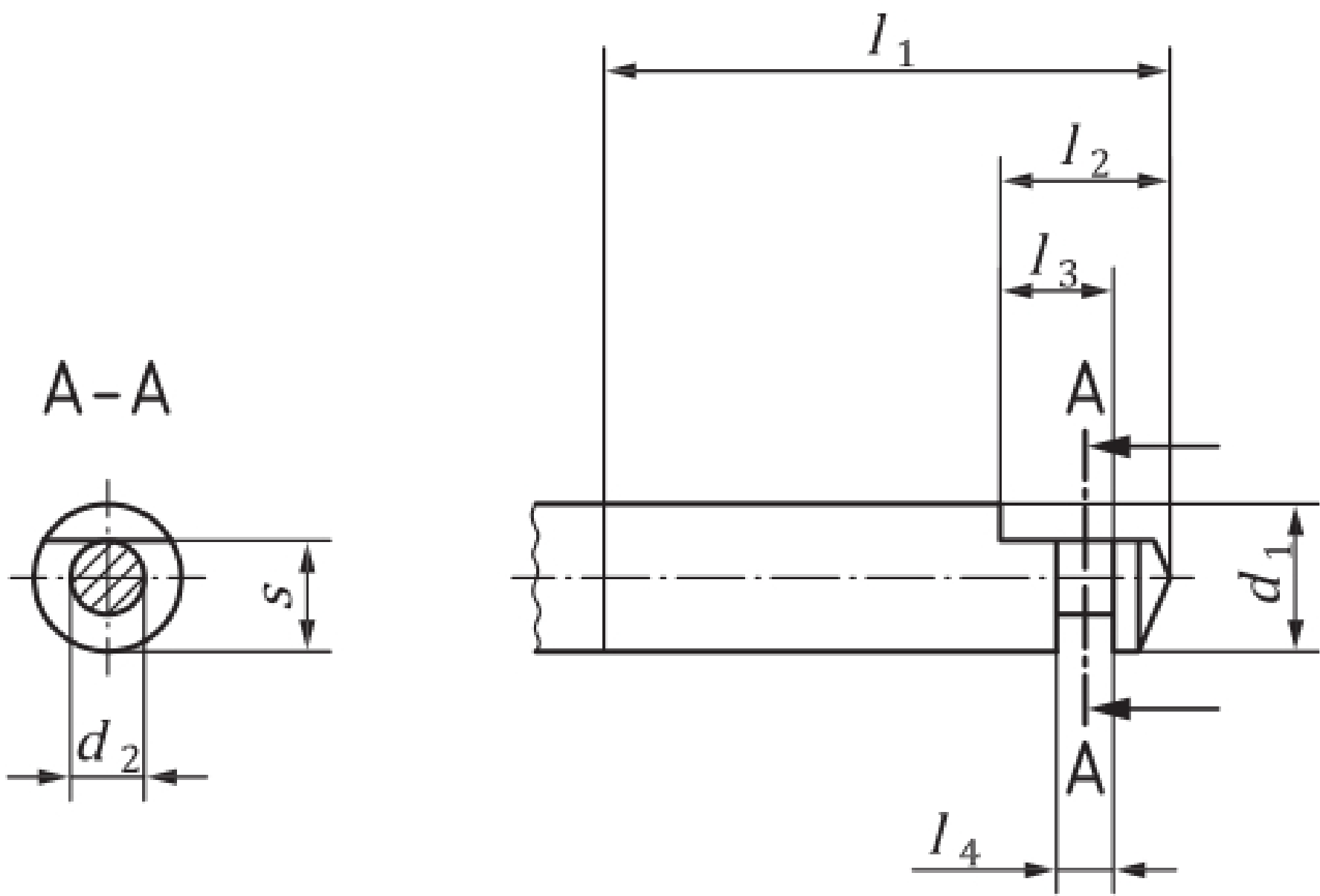


Figure 2 — Type 1 shank

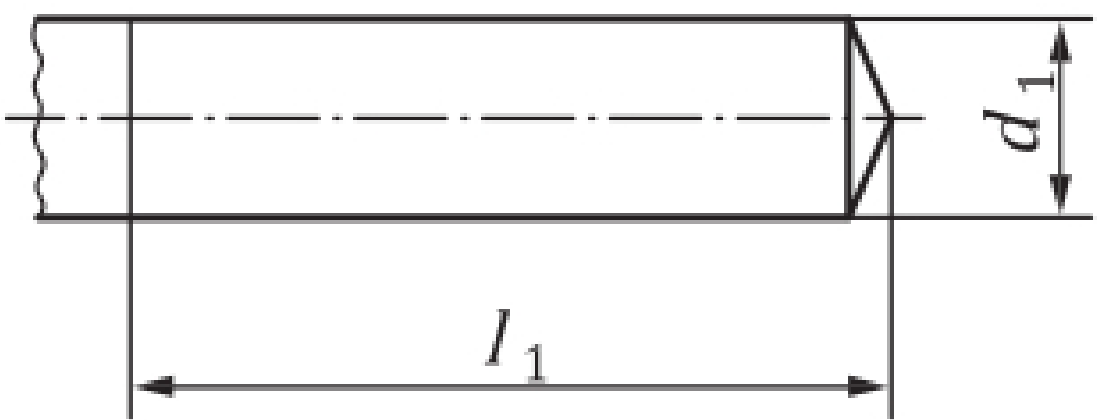


Figure 3 — Type 2 and Type 4 shank

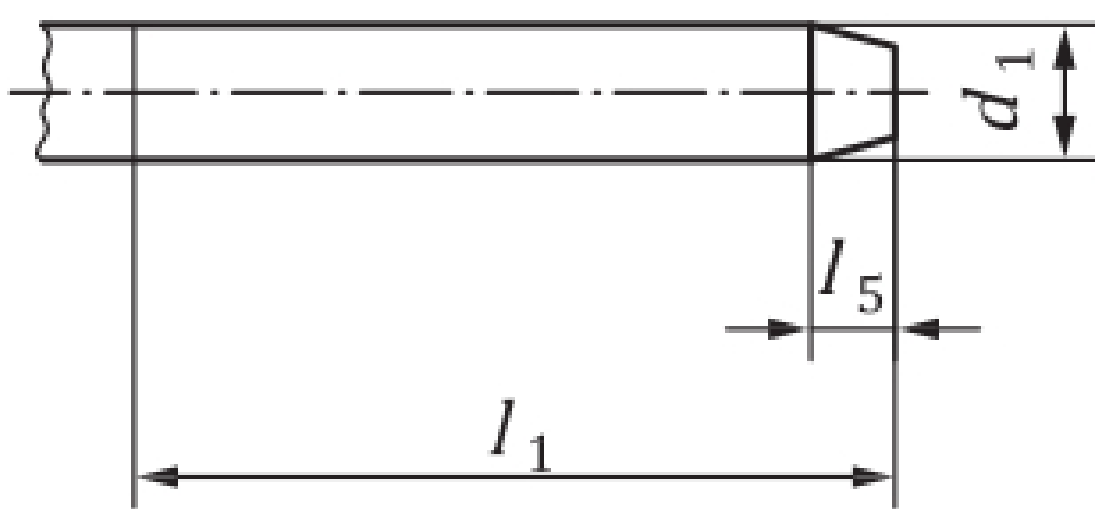


Figure 4 — Type 3 shank

5 Requirements

5.1 Dimensions

5.1.1 Dimensions of shanks made of metal, tungsten carbide or ceramic material

The dimensions and tolerances for shanks made of metal, tungsten carbide or ceramic material shall be as shown in [Figure 5](#), [Figure 6](#), [Figure 7](#) and [Figure 8](#) and as given in [Table 1](#).

Dimensions are given in millimetres and surface roughness in micrometres.

The end of the shank for Type 1, Type 2 and Type 4 shall be flat, conical or rounded. The end of the shank for Type 3 shall be conical or rounded.

Test in accordance with [7.1](#) to [7.4](#).

Table 1 — Fitting length of shank

Dimensions in millimetres

Shank	Diameter	Fitting length, $l_1$ min.		
		Miniature, short	Standard, long	Extra long
Type 1 <sup>a</sup>	2,35	9	11	12
Type 2	2,35	15	30	30
Type 3	1,6	9	11	12
Type 4	3	—	30	30

<sup>a</sup> The start of any enlargement on a Type 1 shank (e.g. by marking or the working head) shall be outside the fitting length.

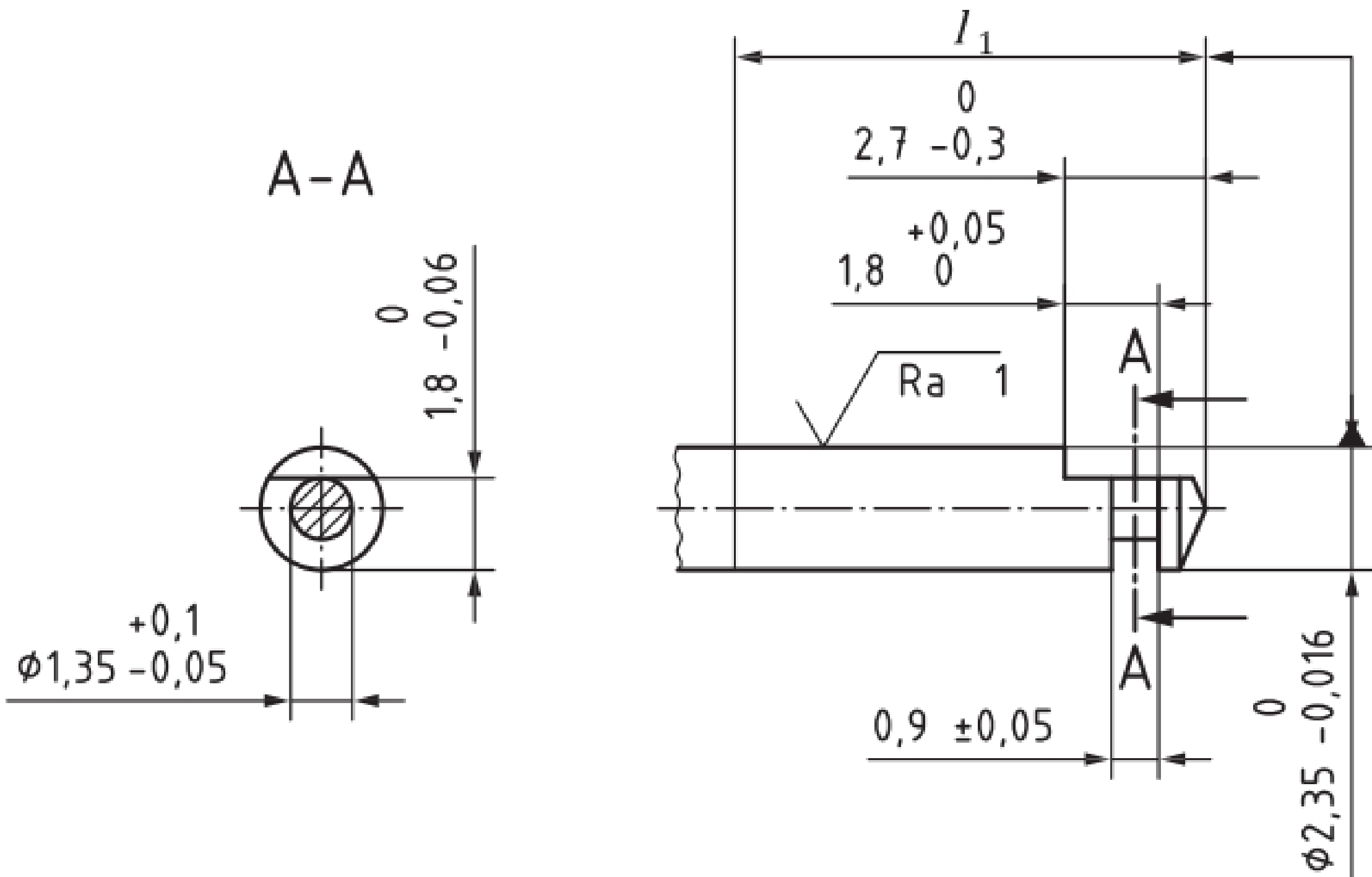


Figure 5 — Dimensions, tolerances and surface roughness for Type 1 shank



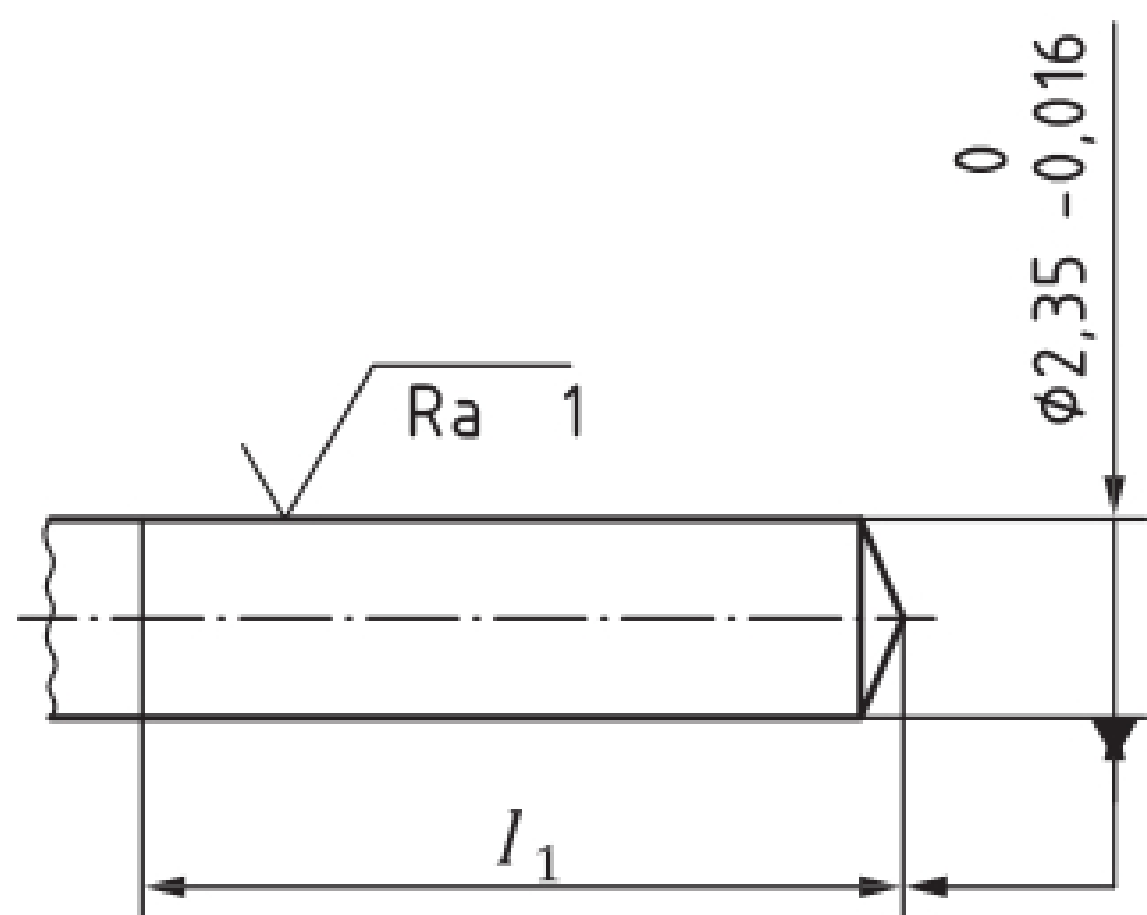


Figure 6 — Dimensions, tolerances and surface roughness for Type 2 shank

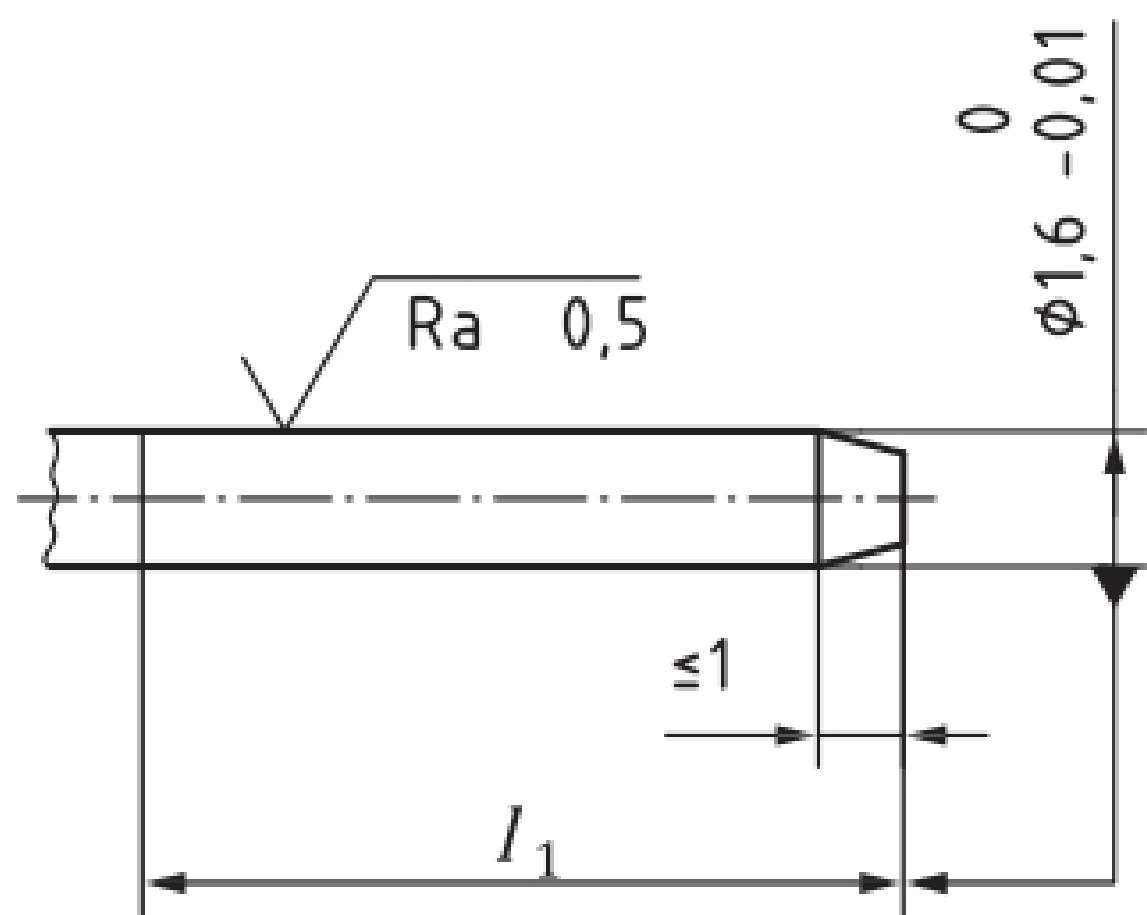


Figure 7 — Dimensions, tolerances and surface roughness for Type 3 shank

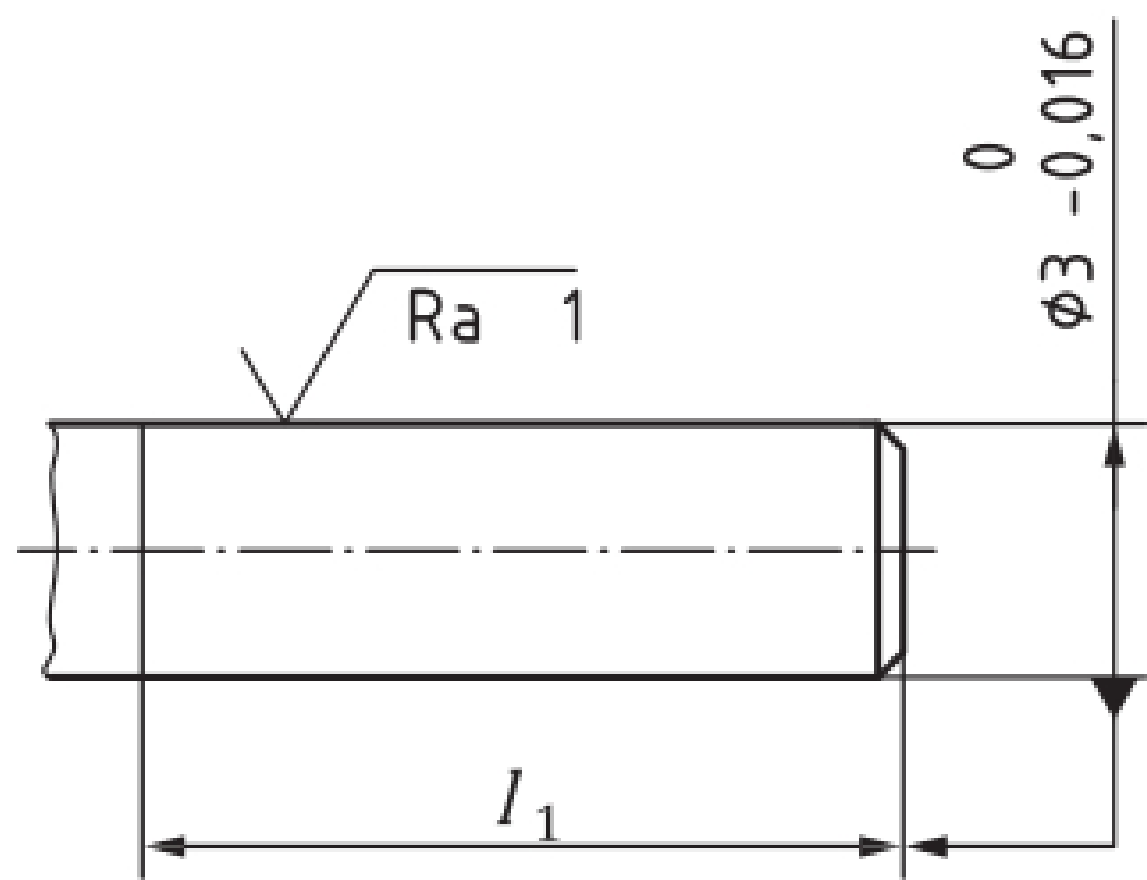


Figure 8 — Dimensions, tolerances and surface roughness for Type 4 shank

### 5.1.2 Dimensions of Type 1 plastic shanks

#### 5.1.2.1 General

The dimensions and tolerances for Type 1 plastic shanks shall be as shown in [Figure 9](#) and [Figure 10](#).

Dimensions are given in millimetres and surface roughness in micrometres.

The fitting lengths shall be in accordance with [Table 1](#).

The end of the shank for Type 1 shall be flat, conical or rounded.

Test in accordance with [7.1](#) to [7.4](#), if applicable.

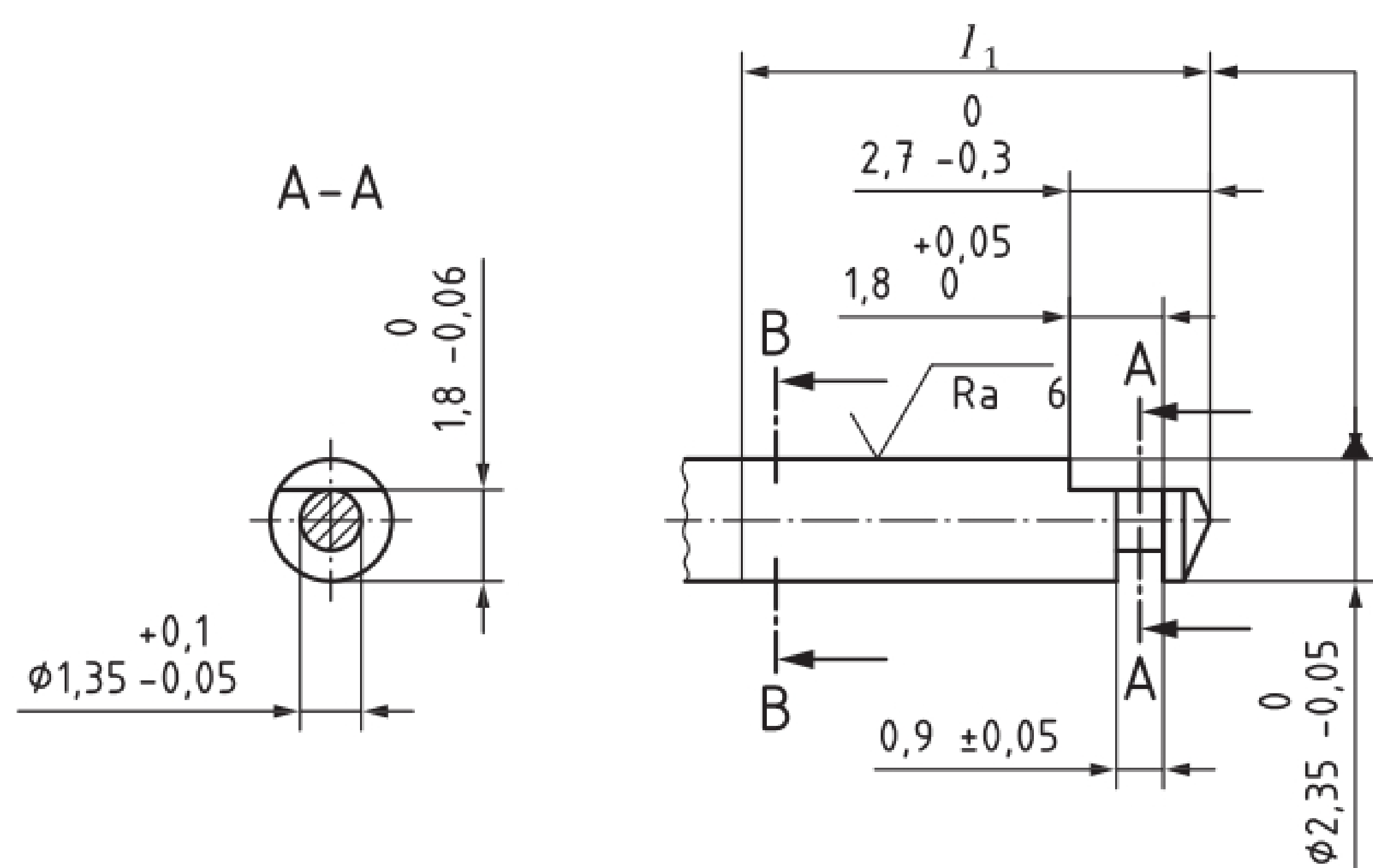


Figure 9 — Dimensions, tolerances and surface roughness for Type 1 plastic shank

5.1.2.2 Permitted shape deviations — Flattened portions of plastic shanks

Surface irregularities shall comply with the following specifications (see [Figure 10](#)).

- $d_1 = 2,35_{-0,05}^0$  mm ;
- $x = \text{max. } 0,04$  mm;
- $d_3 \leq d_1$ ;
- $y = \text{max. } 0,04$  mm.

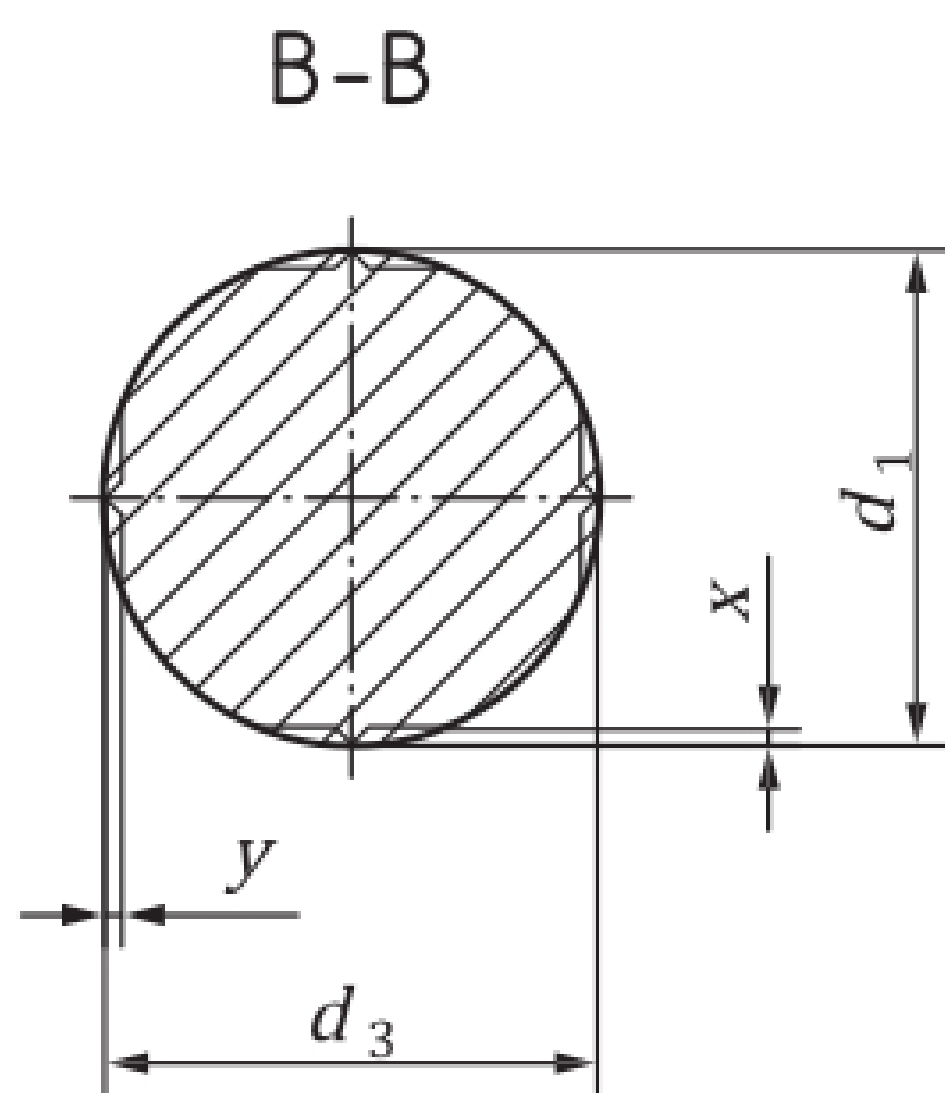


Figure 10 — Flattened portions, cross-section B-B of [Figure 9](#)

5.1.3 Shank cylindricity

The shank cylindricity for all shanks shall be within the tolerances of the acceptable shank diameter.

The definition of cylindricity is given in ISO 1101 .

Test in accordance with [7.3](#).

#### 5.1.4 Surface roughness

The surface roughness,  $Ra$ , for shanks made of metal, tungsten carbide or ceramic material, shall be for the following, as shown in [Figure 5](#) to [Figure 8](#):

- a) Type 1, Type 2, and Type 4:  $\leq 1 \mu\text{m}$ ;
- b) Type 3:  $\leq 0,5 \mu\text{m}$ .

The surface roughness for polymeric materials  $Ra$ , shall be  $\leq 6 \mu\text{m}$  for all types.

Test in accordance with [7.4](#).

#### 5.1.5 Location of marking

The location of the marking, if envisaged, should be outside the fitting length.

If the marking is applied within the fitting length,  $l_1$ , the outside diameter of the shank with the marking shall not exceed the effective diameter of the shank.

Testing shall be carried out by visual inspection.

#### 5.1.6 Colour code of plastic shanks

The colour of the plastic shanks shall comply with the colour code of the instrument for which it is used.

Testing shall be carried out by visual inspection.

### 5.2 Material requirements

#### 5.2.1 Shanks made of metal or tungsten carbide

##### 5.2.1.1 Type of material for metal or tungsten carbide shanks

The exact type of metal or tungsten carbide material and the treatment given to it are at the discretion of the manufacturer.

##### 5.2.1.2 Hardness for metal or tungsten carbide shanks

The hardness for shanks made of metal or tungsten carbide shall be not less than 250 HV5.

Test in accordance with [7.5](#).

#### 5.2.2 Shanks made of ceramic materials

##### 5.2.2.1 Type of material for ceramic shanks

The exact type of ceramic material and the treatment given to it are at the discretion of the manufacturer.

##### 5.2.2.2 Hardness for ceramic shanks

The hardness for shanks made of ceramic material shall be not less than 1 400 HV0,5.

Test in accordance with [7.5](#).

### 5.2.3 Shanks made of plastic materials

#### 5.2.3.1 Type of material for plastic shanks

The exact type of plastic material and the treatment given to it are at the discretion of the manufacturer.

#### 5.2.3.2 Tensile test for plastic shanks

The tensile strength for shanks made of plastic shanks shall be not less than 130 MPa.

Testing shall be carried out in accordance with [7.6](#).

#### 5.2.3.3 Heat resistance and colour stability for plastic shanks

This requirement does not apply to single use instruments.

Shanks made of plastic material shall show no signs of deformation and there shall be no recognizable colour change after testing.

Testing shall be carried out in accordance with [7.7](#).

#### 5.2.3.4 Stability against swelling and chemicals for plastic shanks

This requirement does not apply to single use instruments.

Shanks made of plastic materials shall not swell beyond the specified tolerance range of [Figure 5](#) to [Figure 9](#) when treated with disinfecting or sterilizing solutions as recommended by the manufacturer. Shanks shall meet the tolerance range of [Figure 9](#) when sterilized according to [7.7](#).

Testing shall be carried out in accordance with [7.1](#) to [7.3](#).

#### 5.2.3.5 Marking

Marking shall be resistant to reprocessing procedures as disinfection, cleaning and sterilization for at least five cycles according to the manufacturer's instructions, unless the instrument is marked for single use.

## 6 Sampling and pass/fail evaluation

Take 10 instruments at random from the validation batch and test them according to the method described in [Clause 7](#).

If eight or fewer instruments pass, the product fails.

If nine instruments pass, test 10 additional instruments. When 10 additional instruments are tested, all 10 additional instruments shall pass for the product to comply.

## 7 Measurement and test methods

### 7.1 Shank diameter

Measurements of the shank diameter shall be made in accordance with ISO 8325 with suitable measuring devices. The manufacturer shall validate that the accuracy of the measuring device is applicable.

The shank diameter,  $d_1$ , shall be measured by traversing the length,  $l_1$ .

## 7.2 Other dimensions

Measurements of other dimensions shall be made in accordance with ISO 8325 with suitable measuring devices. The manufacturer shall validate that the accuracy of the measuring device is applicable.

## 7.3 Shank cylindricity

Use a test method based on, for example, run-out test methods or straightness measuring techniques with at least three point locations during the qualification process.

## 7.4 Surface roughness

Test the surface roughness in accordance with ISO 3274 and ISO 4288.

## 7.5 Vickers hardness

Test the Vickers hardness in accordance with ISO 6507-1. The test is applicable for shanks made of metal and tungsten carbide.

For ceramic shanks, test the hardness in accordance with EN 843-4 or ISO 6507-1.

## 7.6 Tensile strength (only for shanks made of plastic materials)

Test the tensile strength in accordance with ISO 527-2.

The test is applicable for shanks made of plastic materials.

## 7.7 Heat resistance, colour stability and stability against swelling (only for shanks made of plastic materials)

### 7.7.1 Apparatus

Steam autoclave.

### 7.7.2 Procedure

Autoclave 10 instruments of each size under pressure of 220 kPa (2,2 bar) at  $(134 \pm 2) ^\circ\text{C}$  for 20 min.

### 7.7.3 Swelling resistance during reprocessing

Use a single reprocessing cycle according to the manufacturer's instruction. After cooling down to room temperature and drying to ensure that the material is dry enough, measure the diameter within 2 h.

Annex A  
(informative)

Quality control

A.1 Types of shank

For the purpose of quality control, the shanks of the instruments shall be classified as given in [Clause 4](#).

A.2 Defects

A.2.1 Major defects

Major defects shall be those deviations from the specifications listed in [Table A.1](#). Major defects include only those items which prevent an instrument from operating or from functioning properly.

A.2.2 Minor defects

Minor defects shall be all deviations in fitting dimensions not listed in [Table A.1](#). Minor defects include all other deviations from the specification which lower the quality of the instrument, but do not prevent them to operate properly.

Table A.1 — Major defects

Shank	$d_1$	$d_2$	$l_3$	$l_4$	$s$
Type 1	>2,35 <2,334 <2,3 (only for plastic shanks)	>1,45	<1,80	<0,85	>1,80
Type 2	>2,35 <2,334	—	—	—	—
Type 3	>1,60 <1,59	—	—	—	—
Type 4	>3,00 <2,984	—	—	—	—



Bibliography

[1] ISO 2859-1 , *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

[2] ISO 3630-1 , *Dentistry — Root-canal instruments — Part 1: General requirements and test methods*

[3] EN 843-4 , *Advanced technical ceramics — Mechanical properties of monolithic ceramics at room temperature — Part 4: Vickers, Knoop and Rockwell superficial hardness*

