SRI LANKA STANDARD 276 : 2013 UDC 687.972

## SPECIFICATION FOR TOOTHBRUSHES (Third Revision)

SRI LANKA STANDARDS INSTITUTION

SRI LANKA STANDARD SPECIFICATION FOR TOOTHBRUSHES (Third Revision)

SLS 276 : 2013 (Attached AMD 474, AMD 513, AMD 536)

**Gr. 8** 

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#### SRI LANKA STANDARD SPECIFICATION FOR TOOTHBRUSHES (Third Revision)

#### FOREWORD

This Sri Lanka Standard was approved by the Sectoral Committee on Chemical and Polymer Technology and authorized for adoption and publication as a Sri Lanka Standard by the Council of the Sri Lanka Standards Institution on 2013-10-30.

This specification was first published in 1974, followed by the First Revision in 1989 and the Second Revision in 2007. The Third Revision is issued to cover the toothbrushes with dual textured /multi textured filaments. A new test method for the determination of the strength of the shaft has been included instead of the test method for the determination of handle impact strength specified in Amendment 02. Technical contents specified in Amendment 02 have been incorporated in to this Revision.

A toothbrush shall provide efficient cleaning of the tooth surfaces. It should not cause tooth abrasion or intra oral injuries. The performance of a toothbrush will depend not only on the material and construction but also on its shape, design and the method of brushing teeth. Although an ideal shape and design for a toothbrush could not be prescribed, recommendations made by the experts in dental and oral hygiene have been considered in this Specification. The filaments should be round ended to reduce the potential for any unwanted effects such as injury to soft tissue, abrasion, etc.

With the view of accommodating different varieties of toothbrushes available in the market, requirements have been specified for the number of filaments per toothbrush, instead of specifying the number of filaments per tuft.

This specification is subject to the restrictions imposed under the Cosmetics, Devices and Drugs Act No. 27 of 1980, Consumer Affairs Authority Act No. 09 of 2003 and the Regulations framed thereunder.

For the purpose of deciding whether a particular requirement of this specification is complied with, the final value, observed or calculated, expressing a result of a test or an analysis, shall be rounded off in accordance with **SLS 102**. The number of significant places retained in the rounded off value shall be the same as that of the specified value in this specification.

In the preparation of this specification, the assistance obtained from the following publications is gratefully acknowledged.

IS 3387 : 2004 Specification for toothbrush SANS 1374 : 2008 Toothbrushes

## 1 SCOPE

**1.1** This specification prescribes the requirements, methods of sampling and tests for toothbrushes having tufts of synthetic filaments and intended to be used manually for oral hygiene as a general cleaning device.

**1.2** It does not cover toothbrushes with natural bristle tufts or electrically operated toothbrushes. Specialized tooth cleaning devices designed for specific oral conditions are also outside the scope of this specification.

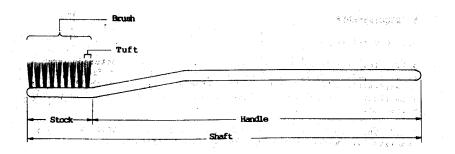
#### 2 **REFERENCES**

- SLS 102 Rules for rounding off numerical values
- SLS 428 Random sampling methods

### **3 DEFINITIONS**

For the purpose of this specification the following definitions shall apply (see Figure 1):

- **3.1 brush** : The part of the toothbrush that comprises the tufts.
- **3.2 handle** : The part of the toothbrush which is not defined as the head.
- **3.3 head** : The stock and the brush of the toothbrush.
- **3.4 shaft** : The complete toothbrush except the tufts.
- **3.5 stock** : The extension of the handle which supports the tufts.
- **3.6 filament** : A single element of a tuft fixed in to a brush
- **3.7 tuft** : The aggregate of the filaments that are fixed in one hole in the stock.



## FIGURE 1 – Different parts of a toothbrush

## 4. SIZES AND TYPES

Toothbrushes shall be classified into the following sizes and types as given in Table 1. The type is defined based on the diameter of the filaments (5.2.8) used in the toothbrush.

<b>Sl. No.</b> (1)	Size (2)	<b>Type(s)</b> (3)
i)	Adult	Medium / soft / extra soft or combination of these
ii)	Junior and Baby	Soft / extra soft or combination of these

**TABLE 1- Sizes of toothbrushes and types** 

## 5 **REQUIREMENTS**

## 5.1 General requirements

**5.1.1** The shaft of the toothbrush shall be manufactured from a suitable food grade plastic material (see Note 1) of specified strength (see **5.2.5**) and free from any objectionable odour or taste. All surfaces of the shaft shall be free from sharp edges and sharp corners which may cause injury to the user during normal use. The shaft of the toothbrush shall not get soften when kept immersed in water at  $65 \pm 2$  °C for 30 minutes.

**5.1.2** The handle of the brush shall be flat and with a firm grip.

**5.1.3** The stock of the toothbrush shall have a sufficient thickness to allow the tufting of the filaments so as to meet the stipulated pull strength requirement (see **5.2.7**).

**5.1.4** The filaments shall be of nylon 6.6, 6.10, 6.12 or any other synthetic materials, provided that evidence is produced to the testing authority to show that their relevant physical properties and clinical effectiveness are at least equal to those of nylon 6.6, 6.10 or 6.12. The filaments shall be smooth and they shall not be wavy or twisted.

**5.1.5** During normal usage, any colouring material added in the manufacture of toothbrushes shall be in food grade and free fast (see Notes).

## NOTES :

*1* Food grade certificates for raw materials/colouring materials issued by the manufacturer and certified by a recognized body are accepted.

2 Change in colour of the filaments, if any, indicates the user that it needs replacement (generally after a period of approximately 3 months).

## 5.2 Other requirements

**5.2.1** Toothbrushes of adult, junior and baby sizes shall conform to the requirements specified in Table **2**.

## 5.2.3 Tufting

**5.2.3.1** The material used for tufting shall be suitable non-corrosive materials.

**NOTE :** Filaments may be fixed to stock using any suitable technology such as staple technology, welding technology, fusion technology, in-mould welding technology, etc.

**5.2.3.2** The technology used for tufting shall conform to the requirement for pull strength (see **5.2.7**). There shall be no evidence of dislodgement of tufts when tested by the method prescribed in Appendix **B**.

## **5.2.4** *Filament bend recovery*

The bend recovery of the filament shall be not less than 40 per cent when tested by the method prescribed in Appendix C.

## **5.2.5** *Strength of the shaft*

The shaft of a toothbrush shall not break when tested by the method prescribed in Appendix **D**.

## **5.2.6** *End rounding of filaments*

The end rounding of filaments shall be not less than 60 per cent when tested by the method prescribed in Appendix E.

## 5.2.7 Pull strength

The force required for pulling out an individual tuft shall be not less than 1.0 kg when tested by the method prescribed in Appendix **F**.

## 5.2.8 Diameter of filaments

Diameter of filaments shall be 0.23 mm to 0.27 mm for Medium type, 0.18 mm to 0.22 mm for Soft type and 0.1 mm to 0.15 mm to for Extra soft type.

Sl	Characteristic	Requirements for toothbrushes		
No.		Adult	Junior	Baby
		(3)	(4)	(5)
(1)	(2)			
i)	Overall length* (Length of the shaft), mm, min.	150	120	90
ii)	Width of stock*, mm, max.			
	a) for rectangular shape	13	12	09
	b) for other shapes	13	12	09
	b) for other shapes	11	12	0,7
iii)	Length of brush**, mm (See Note <b>4</b> )	18 to 28	10 to 20	10 to 15
iv)	Distance beyond a line tangential to the outermost points on the outermost tuft holes in the stock, mm, max.			
	a) in transverse axis	02	02	02
		02	02 03	02 03
	b) in longitudinal axis	03	05	03
v)	Length of filaments, mm (See Note 1)	10 to 12	9 to 12	9 to 12
vi)	Contouring variation of brush, mm (See Note <b>2</b> )	0-2	0-2	0-2
vii)	Number of tufts, min.	20	18	10
viii)	Number of filaments per toothbrush, min. (See Note <b>3</b> )	700	500	500

## TABLE 2 – Requirements for medium and soft toothbrushes

\* See Figure 1

\*\* The measurement shall be made at the bottom of the two tufts at extreme ends considering the longer side of the stock.

#### NOTES :

- 1. The filament length is measured from the point at which the filament enters the stock.
- 2. The contouring variation of brush is the difference in height between the highest and the lowest tuft.
- 3. The number of filaments refers to the number of free ends of filaments in a toothbrush.
- 4. Length of brush is adhered to the minimum range as far as possible.

## 6 PACKAGING AND MARKING

**6.1** Each toothbrush shall be suitably and hygienically packed to prevent contamination under normal retail handling conditions. Each pack shall be legibly and indelibly marked with the following :

- a) Name of the product ;
- b) Size of the toothbrush ;
- c) Type (see 6.4);
- d) Name and address of the manufacturer for locally manufactured products;
- e) Name and address of the distributor / importer in Sri Lanka including the country of origin, in the case of imported products ;
- f) Registered trade mark, if any ;
- g) Brand name, if any ; and
- h) Batch or code number.

**6.2** A number of such containers with toothbrushes of the same size and type shall be packed together, in a manner acceptable to the purchaser. Each package shall be legibly and indelibly marked with the following :

- a) Name of the product ;
- b) Size;
- c) Type (see **6.4**);
- d) Name and address of the manufacturer for locally manufactured products;
- e) Name and address of the distributor / importer in Sri Lanka including the country of origin, in the case of imported products ;
- f) Registered trade mark, if any ;
- g) Brand name, if any ; and
- h) Batch or code number ; and
- j) Date of manufacture.

6.3 Each toothbrush shall be legibly and indelibly marked with the following :

- a) Registered trade mark , if any ; and
- b) Brand name, if any.

**6.4** To indicate the type of dual-textured or multi-textured toothbrushes, having different quantities of filaments of different diameters, the texture of highest number of filaments shall be indicated first, for instance medium/soft indicates that there are more medium filaments than soft. For dual-textured or multi-textured toothbrushes having equal quantities of filaments of different diameters, the texture of the largest diameter filament shall be indicated first.

## NOTE :

- 1. It is recommended that the packages carry public health messages such as,
- *a) Correct brushing helps teeth last a life time.*
- *b) Teeth are for a life time.*

- *c) Regular brushing helps maintain good oral teeth.*
- *d) Change in colour and or shape of filaments indicate the toothbrush is not suitable to use.*

6.5 A number of such packages with toothbrushes of the same size and type may in turn be packed in a carton. Marking on the carton shall be in accordance with 6.2.

## 7 SAMPLING

The method of drawing representative samples of the product for ascertaining conformity to the requirements of this specification shall be prescribed in Appendix **A**.

## 8 METHODS OF TEST

Tests shall be carried out as prescribed in Appendices **B** to **F** of this specification.

## APPENDIX A COMPLIANCE OF A LOT

Sampling scheme given in this Appendix should be applied where compliance of a lot to the requirements of this standards is to be assessed based on statistical sampling and inspection.

## A.1 LOT

In any consignment all the packages of toothbrushes of the same size and type and belonging to one batch of manufacture or supply shall constitute a lot.

## A.2 SCALE OF SAMPLING

**A.2.1** The samples shall be tested from each lot for ascertaining conformity to the requirements of this specification.

A.2.2 The number of packages to be selected from a lot shall be in accordance with Table 3.

Number of packages in the lot (1)	Number of packages to be selected (2)	
Up to 100	04	
101 to 200	06	
201 to 300	09	
301 to 500	13	
501 and above	20	

TABLE 3 – Sca	ale of sampling
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**A.2.3** If the packages are packed in cartons, 10 per cent of the cartons, subject to a minimum of three shall be selected. As far as possible an equal number of packages shall be selected from each carton to form a sample in accordance with **A.2.2**.

A.2.4 The cartons and packages shall be selected at random. In order to ensure randomness of selection, tables of random numbers conforming to SLS 428 shall be used.

## A.3 NUMBER OF TESTS

**A.3.1** Each carton and/or package selected in accordance with **A.2.2** or **A.2.3** shall be inspected for packaging and marking requirements.

A.3.2 One container shall be selected from each package selected in accordance with A.2.2 or A.2.3 and the container and the toothbrush shall be examined for packaging and marking requirements.

A.3.3 One toothbrush shall be selected from each package selected in accordance with A.2.2 or A.2.3 and tested for the characteristics i), ii), iii), iv) and viii) given in Column 1 of Table 2 and the shaft of the each tested toothbrush shall be tested for the softening of the shaft (see 5.1.1).

**A.3.4** One toothbrush shall be selected from each package selected in accordance with **A.2.2** or **A.2.3**. Six filaments from each toothbrush so selected shall be tested for length of filaments and diameter of filaments (see Note). Each toothbrush shall also be tested for the number of filaments per toothbrush and strength of shaft.

**NOTE** : When testing for dual textured or multi textured toothbrushes having filaments of different diameters, the filaments are to be selected from different places and as far as possible an equal number of filaments are to be tested from each type of textural stiffness.

**A.3.5** Three toothbrushes shall be selected from each package selected in accordance with **A.2.2** or **A.2.3** and tested for contouring variation of brush and end rounding of filaments.

**A.3.6** Two toothbrushes shall be selected from each package selected in accordance with **A.2.2** or **A.2.3** and two tufts in each toothbrush shall be tested for tuft anchorage.

**A.3.7** Thirty filaments used for the manufacture of toothbrushes shall be obtained from the manufacturer and tested for filament bend recovery.

**A.3.8** Two toothbrushes shall be selected from each package selected in accordance with **A.2.2** or **A.2.3** and two tufts in each toothbrush shall be tested for the pull strength.

## A.4 CRITERIA FOR CONFORMITY

A lot shall be declared as conforming to the requirements of this specification if the following conditions are satisfied :

A.4.1 Each carton and package inspected in accordance with A.3.1 satisfies the relevant requirements.

A.4.2 All containers and toothbrushes examined in accordance with A.3.2 satisfies the relevant requirements.

A.4.3 Each toothbrush examined in accordance with A.3.3 satisfies the relevant requirements.

A.4.4 Each toothbrush examined in accordance with A.3.4 for number of filaments per toothbrush and strength of shaft satisfies the relevant requirements.

A.4.5 The values of the expressions  $\overline{x} - 0.8s$  (see Note 1 and Note 2) and  $\overline{x} + 0.8s$  calculated using the test results on length of filaments lie between the two relevant specification limits.

A.4.6 The values of the expressions  $\overline{x} - 0.8s$  and  $\overline{x} + 0.8s$  calculated using the test results on the diameter of filaments lie between the two relevant specification limits (See Note1,2 and 3).

#### NOTES :

1. Mean  $(\bar{x}) =$  The sum of values of the observations divided by the number of observations.

2. Standard deviation (S) = The positive square root of the quotient obtained by dividing the sum of squares of the deviations of the observations from their mean by one less than the number of observations in the sample.

**NOTE** : In the case of dual- textured or multi-textured toothbrushes, the values of expressions  $\overline{x} - 0.8s$  and  $\overline{x} + 0.8s$  are to be calculated separately for different types of textural stiffness.

A.4.7 Each toothbrush tested in accordance with A.3.5 satisfies the relevant requirements.

A.4.8 Each tuft tested in accordance with A.3.6 satisfies the relevant requirements.

A.4.9 The filaments tested in accordance with A.3.7 satisfies the relevant requirements.

A.4.10 Each toothbrush tested in accordance with A.3.8 satisfies the relevant requirements.

#### APPENDIX B DETERMINATION OF TUFT ANCHORAGE

#### **B.1 APPARATUS**

**B.1.1** A means of securely gripping the stock, so that the free ends of the tufts are left exposed and accessible.

**B.1.2** A means of gripping the free ends of a single tuft and applying a force of 15 N.

#### **B.2 PROCEDURE**

Immerse the head of the toothbrush in a 10 g per 100 ml solution of sodium chloride for 48 hours at room temperature. Grip the stock and gradually apply for a force of 15 N to a single tuft in a direction perpendicular to the stock. Observe the tuft for any dislodgement.

#### APPENDIX C DETERMINATION OF FILAMENT BEND RECOVERY

#### C.1 APPARATUS

**C.1.1** *Metal plate,* with three holes drilled in it as shown in Figure 2. The diameter of the holes shall be 1.5 mm, 2.5 mm and 3.5 mm. The tolerance of the diameters shall be 0.1 mm.

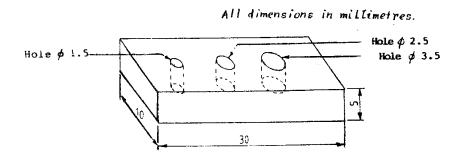


FIGURE 2 – Drilled metal plate

C.1.2 *Water bath*, maintained at  $27 \pm 2$  °C and  $50 \pm 2$  °C.

#### C.2 PROCEDURE

C.2.1 Condition the filaments by immersing in water at a temperature of  $27 \pm 2$  °C for 18 hours.

C.2.2 Lay the filament centrally across the hole in the metal plate (see C.1.1) and gently press it into the hole using a matchstick or soft blunt instrument, so that the filament does not become kinked. Ensure that the filament is correctly positioned as shown in Figure 3 so that it does not protrude by more than the radius of the hole.

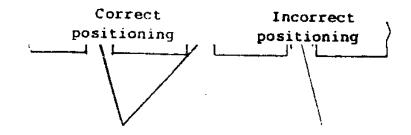


FIGURE 3 - Positioning of filament

**C.2.3** Immerse the metal plate with the filament in the water bath at  $50 \pm 2 \degree C$  for 2 minutes and then in the water bath at  $27 \pm 2 \degree C$  for 30 seconds. Remove the plate, gently remove the filament from the hole and place the filament in a petri dish full of water at  $27 \pm 2 \degree C$ . After immersion for 15 minutes remove the filament and measure the included angle as shown in Figure 4. Ensure that the bent filament is lying flat on a smooth surface. Carry out this test using ten filaments.

C.2.4 Repeat the test for the other two holes.

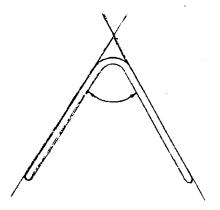


FIGURE 4 – Included angle of recovered filament

### C.3 CALCULATION

**C.3.1** Bend recovery, per cent = included angle  $X \frac{100}{180}$ 

Calculate the average value of bend recovery, separately for each hole.

C.3.2 Plot the average bend recovery against strain (See Figure 5) which is calculated from,

$$Strain = \frac{d}{(D-d)}$$

where

- d is the diameter, in millimetres, of the filament ; and
- D is the diameter, in millimetres, of the hole.

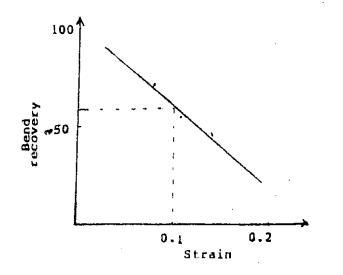


FIGURE 5 – Typical recovery vs strain plot

C.3.3 Read off the percentage recovery at a strain of 0.1.

#### APPENDIX D DETERMINATION OF STRENGTH OF THE SHAFT

#### **D.1 APPARATUS**

- **D.1.1** A means of supporting the shaft at both ends with the shaft horizontal.
- **D.1.2** A means of applying a force of 15 N perpendicular to the shaft.

#### **D.2 PROCEDURE**

**D.2.1** Support the shaft horizontally with the brush uppermost, on two supports placed 10 mm from each end of the shaft.

**D.2.2** Midway between the two supports apply a force of 15 N perpendicular to the shaft, to the upper surface of it and across its whole width. Maintain the load for 5 minutes.

#### APPENDIX E DETERMINATION OF END ROUNDING

### E.1 APPARATUS

Simple or compound microscope (recommended) with adequate magnification to observe the end rounding of filament tips.

#### **E.2 PROCEDURE**

**E.2.1** Select three closest tufts to the top and bottom ends of toothbrush head avoiding the outer line tufts. Care shall be taken to select those tufts to represent the both ends (top and bottom) of brush head to ensure the maximum area coverage.

**E.2.2** Count number of tips in each selected tufts  $-E_1$ ,  $E_2$ ,  $E_3$ .

where

 $E_1$  is the number of tips in first tuft ;

 $E_2$  is the number of tips in second tuft ; and

 $E_3$  is the number of tips in third tuft.

**E.2.3** While rotating, observe the end rounding of the tips from each selected tuft under the microscope and count the number of tips with acceptable end rounding. The tips with any sort of sharp angles/corners or edges shall be unacceptable and those without shall be acceptable (see Figure 6). Record the acceptable number of tips in each tuft.

where

 $N_1$  is the number of acceptable tips in first tuft ;

- $N_2$  is the number of acceptable tips in second tuft ; and
- $N_3$  is the number of acceptable tips in third tuft.

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#### E.2.4 Calculation

End rounding, per cent  $= \frac{(N_1 + N_2 + N_3)}{E_1 + E_2 + E_3} X$  100

E.2.5 Repeat the same procedure for two more toothbrushes.

E.2.6 Take average of end-rounding of three toothbrushes.

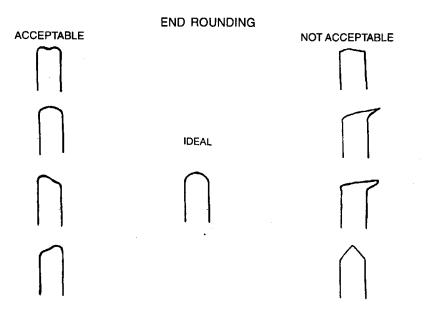


FIGURE 6 – Guideline for acceptable and unacceptable end rounding

#### APPENDIX F DETERMINATION OF PULL STRENGTH

#### F.1 APPARATUS

A simple instrument as shown in Figure 7 can be used for testing the pull strength. This unit is suitable for mounting on wall. It consists of a dial force gauge/weighing scale operating or spring (B) mounted on wooden plate (A). A tubular tuft-holder (C) is hung on the hook of dial gauge. A clamp for holding toothbrush (E) is provided which is movable downward and upward with a screw (G).

**NOTE** : Manufacturer may use sophisticated electronic instrument available in market to determine the pull strength.

#### F.2 PROCEDURE

**F.2.1** Fix a toothbrush head with tufts in upward direction in the toothbrush holder with the help of screw (F).

**F.2.2** Insert all filaments of one tuft in the hole provided at the bottom of tubular tuft – holder (C). Care should be taken not to allow filaments from the adjacent tuft to enter in to the hole. Fix the tuft firmly with the help of screw (D).

**F.2.3** Adjust the pointer on dial to zero by adjustment of screw (G).

**F.2.4** Move down the toothbrush holder slowly with screw (G) watching the pointer on dial carefully. Note down the reading on dial at which the tuft comes out of the hole. This is the pull strength of the tuft.

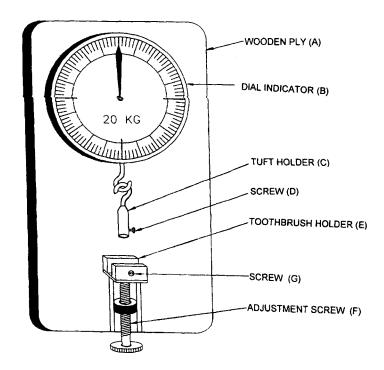


FIGURE 7 – Instrument for determination of pull strength

. . . . . . . . . . . . . . . .

# AMENDMENT NO: 01 APPROVED ON 2016-03-23 TO SLS 276: 2013

## SRI LANKA STANDARD SPECIFICATION FOR TOOTHBRUSHES (THIRD REVISION)

## **EXPLANATORY NOTE**

As a result of new technological development, tooth brushes with different shapes of handle have been introduced in to the market. Therefore considering the impact on safety requirement for the design of the handle has been reviewed.

This amendment is issued considering the above

## AMENDMENT NO: 01 APPROVED ON 2016-03-23 TO SLS 276: 2013 SRI LANKA STANDARD SPECIFICATION FOR TOOTHBRUSHES (THIRD REVISION)

## 5 **REQUIREMENTS**

## 5.1 General requirements

Delete the text given in **5.1.2** and substitute the following:

"The handle of the toothbrush shall be designed to have a firm grip and must not contain any sharp edges".

.....

## AMENDMENT NO: 02 APPROVED ON 2018-11-16 to SLS 276: 2013

# SRI LANKA STANDARD SPECIFICATION FOR TOOTHBRUSHES (THIRD REVISION)

#### **EXPLANATORY NOTE**

This amendment is issued considering the health benefits to the consumer and also the concerns by the industry. Accordingly, Clause **5.2** and Clauses **A.3** and **A.4** of Appendix A have been updated

#### AMENDMENT NO: 02 APPROVED ON 2018-11-16 to SLS 276: 2013

## SRI LANKA STANDARD SPECIFICATION FOR TOOTHBRUSHES (THIRD REVISION)

#### **5 REQUIREMENTS**

#### 5.2 Other requirements

Delete the text given in **5.2.8** and substitute the following:

"Diameter of filaments shall be 0.181 mm to 0.270 mm for Medium type, 0.151 mm to 0.180 mm for soft type and 0.10 mm to 0.150 mm for Extra soft type".

#### **APPENDIX** A

#### A.3 NUMBER OF TESTS

Delete the Note given underneath the A.3.4 and substitute the following:

#### **"NOTE**

When testing for dual textured or multi textured toothbrushes having filaments of different diameters, the filaments are to be selected from different places and as far as possible an equal number of filaments is to be tested from each type of textured stiffness. When testing of toothbrushes with different filament lengths, 06 filaments representing each of the highest and the lowest tufts is to be tested".

#### A.4 CRITERIA FOR CONFORMITY

**NOTE:** In the case of dual- textured or multi-textured toothbrushes, the values of expressions  $\bar{X} - 0.8s$  and  $\bar{X} + 0.8s$  are to be calculated separately for different types of textural stiffness.

Delete the above Note and substitute the following as Note 3:

"3. In the case of dual-textured or multi-textured toothbrushes and tooth brushes with different filament lengths, the values of expressions  $\overline{X} - 0.8s$  and  $\overline{X} + 0.8s$  are to be calculated separately for different filament lengths and diameters.

.....

## Amendment No: 03 Approved on 2020-12-22 to SLS 276 : 2013

# SRI LANKA STANDARD SPECIFICATION FOR TOOTHBRUSHES (*Third Revision*)

### **EXPLANATORY NOTE**

This amendment is issued to overcome the barrier for innovative products to enter the market and also the concerns by the industry. Accordingly, Clause 1, 5.1, 5.2 and 6 have been updated

## Amendment No: 03 Approved on 2020-12-22 to SLS 276 : 2013

# SRI LANKA STANDARD SPECIFICATION FOR TOOTHBRUSHES (*Third Revision*)

#### FOREWORD

Delete the text given in fifth paragraph and substitute the following:

"This Specification is subject to the restrictions imposed under the Consumer Affairs Authority Act No 09 of 2003 and other applicable State Legislative requirements."

#### 1 SCOPE

Delete the text given in **1.2** and substitute the following:

" It does not cover manual toothbrushes for single use, toothbrushes with natural bristle tufts or electrically operated toothbrushes. Specialized tooth cleaning devices designed for specific oral conditions are also outside the scope of this specification."

Insert the following Clause under the Scope

**1.3** "Toothbrushes with particular designs of filament end, filament type or trim profile of which designs are difficult to identify technically, should be evaluated for its biological safety and effectiveness using scientific evidence. Evidences of such studies need to be assessed by a relevant Authority."

#### 5 **REQUIREMENTS**

#### 5.1 General requirements

Delete the "plastic" word given in first sentence of Clause **5.1.1** and substitute the word "virgin polymeric".

Delete the following words given in last sentence of Clause **5.1.4**: "and they shall not be wavy or twisted".

Delete the **NOTE 2** and renumber the **NOTE 1** as Clauses **5.1.6** as follows:

**"5.1.6** Food grade certificates for raw materials/ colouring materials issued by the manufacturer and certified by a recognized body are accepted."

## 5.2 Other requirements

Delete the text given in **5.2.8** and substitute the following:

## 5.2.8 Diameter of filaments

"Diameter of filaments shall be 0.181 mm to 0.270 mm (or mil 8, 9 or 10) for Medium type, 0.151 mm to 0.180 mm (or mil 6 or 7) for Soft type and 0.10 mm to 0.150 mm (or mil 4 or 5) for Extra Soft type.

**NOTE:** "In the event, there is no facility to measure the diameter of filaments to an accuracy given above, corresponding mil sizes together with supportive evidence may be used for evaluation purpose."

## 6 PACKAGING AND MARKING

Insert the following as S. No. j) in Clause 6.1

j) Warning statement "Replace the brush when bristles distorted".

.....

## SLS CERTIFICATION MARK

The Sri Lanka Standards Institution is the owner of the registered certification mark shown below. Beneath the mark, the number of the Sri Lanka Standard relevant to the product is indicated. This mark may be used only by those who have obtained permits under the SLS certification marks scheme. The presence of this mark on or in relation to a product conveys the assurance that they have been produced to comply with the requirements of the relevant Sri Lanka Standard under a well designed system of quality control inspection and testing operated by the manufacturer and supervised by the SLSI which includes surveillance inspection of the factory, testing of both factory and market samples.

Further particulars of the terms and conditions of the permit may be obtained from the Sri Lanka Standards Institution, 17, Victoria Place, Elvitigala Mawatha, Colombo 08.



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#### SRI LANKA STANDARDS INSTITUTION

The Sri Lanka Standards Institution (SLSI) is the National Standards Organization of Sri Lanka established under the Sri Lanka Standards Institution Act No. 6 of 1984 which repealed and replaced the Bureau of Ceylon Standards Act No. 38 of 1964. The Institution functions under the Ministry of Technology & Research.

The principal objects of the Institution as set out in the Act are to prepare standards and promote their adoption, to provide facilities for examination and testing of products, to operate a Certification Marks Scheme, to certify the quality of products meant for local consumption or exports and to promote standardization and quality control by educational, consultancy and research activity.

The Institution is financed by Government grants, and by the income from the sale of its publications and other services offered for Industry and Business Sector. Financial and Administrative control is vested in a Council appointed in accordance with the provisions of the Act.

The development and formulation of National Standards is carried out by Technical Experts and representatives of other interest groups, assisted by the permanent officers of the Institution. These Technical Committees are appointed under the purview of the Sectoral Committees which in return are appointed by the Council. The Sectoral Committees give the final Technical approval for the Draft National Standards prior to the approval by the Council of the SLSI.

All members of the Technical and Sectoral Committees render their services in an honorary capacity. In this process the Institution endeavours to ensure adequate representation of all view points.

In the International field the Institution represents Sri Lanka in the International Organization for Standardization (ISO), and participates in such fields of Standardization as are of special interest to Sri Lanka.

Printed at the Sri Lanka Standards Institution, 17, Victoria Place, Elvitigala Mawatha, Colombo 08