
Izdelki za otroke - Držalo dude - Varnostne zahteve in preskusne metode

Child care articles - Soother holder - Safety requirements and test methods

Artikel für Säuglinge und Kleinkinder - Schnullerhalter - Sicherheitstechnische Anforderungen und Prüfverfahren

Articles de puériculture - Attache sucette - Exigences de sécurité et méthodes d'essai

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ICS:

97.190

Otroška oprema

Equipment for children

oSIST prEN 12586:2021

en,fr,de

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

DRAFT
prEN 12586

June 2021

ICS 97.190

Will supersede EN 12586:2007+A1:2011

English Version

Child care articles - Soother holder - Safety requirements and test methods

Articles de puériculture - Attache sucette - Exigences
de sécurité et méthodes d'essai

Artikel für Säuglinge und Kleinkinder - Schnullerhalter
- Sicherheitstechnische Anforderungen und
Prüfverfahren

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 252.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (prEN 12586:2021) has been prepared by Technical Committee CEN/TC 252 “Child care articles”, the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 12586:2007+A1:2011.

In comparison with the previous edition, the following technical modifications have been made:

- The standard has been completely renewed and a new structure was given. A whole series of new aspects had to be considered.
- The list of materials used currently for soother holders is wider than the list in the former edition, therefore additional materials have been included (silicone, rubber, TPE, leather, resin-bonded materials).
- Introduction: Double testing should be avoided for environmental protection reasons. Therefore, substances regulated by REACH like Phthalates, Nickel are not included any more.
- 7.3: The list of chemical elements to be tested for migration of certain elements has been enlarged to cover 19 elements in accordance to last amendment of Directive 2009/48/EC.
- 7.4: Colour fastness test was changed and split in first action and final action method.
- 7.7: Limits and test methods for Formaldehyde release from different materials have been revised and modified and included in a separate paragraph. The test and the limit for Formaldehyde release is set based on the pragmatic approach that independently of the material type the amount of Formaldehyde migrating from the entire product into saliva simulant shall not exceed the health-based limit.
- 7.8: Migration limits for BPA, Phenol have been revised and set based on the recent amendments of Appendix C to Annex II of Directive 2009/48/EC.
- 7.9 and 7.10: The list of preservatives was enlarged to cover wood and leader preservatives too.
- Annex B: The specific migration limits have been defined based on the migration scenario usually applied in the childcare article standards drafted by TC252 WG5, considering the allocated daily intake, the body weight, and the likely exposure.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

Introduction

Accidents caused by soothers are few and any resulting in the death of a child are almost unknown. However, a small number of children die as a result of accidents where a soother is involved, but in these cases death almost always results from strangulation by a cord being used to hang the soother around the child's neck. Such cords are usually either home-made or made for some other purpose, e.g. a coiled key ring holder.

The main aim of this document is to eliminate the risk of strangulation. This has only been made possible by severely restricting the length of the soother holder. The length should be sufficient for its purpose while not being so long that the strap can encircle the neck and strangle even the smallest child. The lack of reported incidents involving accidents or fatalities since its introduction would suggest that this document has achieved this main aim.

A functional soother holder is not to be considered as a toy. However, a soother holder may contain a part or be designed in such a way as to present a double use. If the soother holder, in addition to its functional use, has a significant play value, it could also be considered as a toy.

Chemical hazards have been considered by the Technical Committee for all construction materials normally encountered in soother holders. Where relevant, requirements have been derived and included in this document. Restrictions for phthalates, for poly aromatic hydrocarbons (PAH) and for the release of nickel have not been included in this document as they are regulated by REACH [1]. Flame retardants are not included as they are regulated by REACH and Regulation (EC) No 1021/2019 [2] and do not have any relevance to functional soother holders.

Products with claimed biocidal effect or intended biocidal action are falling under the scope of Regulation (EU) No 528/2012 concerning the market and use of biocidal products [3].

It is considered that, for organic chemical compounds, the requirements, sample preparation and extraction, and methods of analysis provided in EN 71-9:2005+A1:2007, EN 71-10:2005 and EN 71-11:2005 are suitable for soother holders, except where stated otherwise.

A normative annex has been included which contains translations of warning phrases into the main European languages.

It is recommended that manufacturers and suppliers operate to EN ISO 9001 for quality management systems [4]. It is also recommended that laboratories operate to ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories [5].

1 Scope

This document specifies safety requirements relating to materials, construction, performance, packaging and labelling of soother holders (see B.1).

It includes test methods for the mechanical and chemical requirements specified.

This document is intended to provide safety requirements for soother holders. All products that allow the attachment of a soother intended for babies and young children with any other product are included in the scope. The soother holder has a holding device at one end for the soother, a garment fastener that attaches to any other product, e.g. the child's garment and a connecting device linking these parts. The safety requirements of these other products cannot be considered in this document.

Where a soother holder is considered to have significant play value, the soother holder is expected to meet the safety requirements for toys as stated in the Toy Directive 2009/48/EC [6] in addition to those in this document. The addition of decorations or providing animal shaped fasteners does not automatically make the soother holder a toy. Where there is doubt concerning the classification of a soother holder as a toy, advice can be sought from an EU Toy Notified Body or the Member State's Competent Authority for toys (see B.2).

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.

EN 71-1:2014+A1:2018, *Safety of toys - Part 1: Mechanical and physical properties*

EN 71-3:2019, *Safety of toys - Part 3: Migration of certain elements*

<https://standards.iteh.ai/catalog/standards/sist/281adf4d-5170-48ee-a599-1a2a3d00a4a0/pr-en-12586-2021>

EN 71-9:2005+A1:2007, *Safety of toys - Part 9: Organic chemical compounds - Requirements*

EN 71-10:2005, *Safety of toys - Part 10: Organic chemical compounds - Sample preparation and extraction*

EN 71-11:2005, *Safety of toys - Part 11: Organic chemical compounds - Methods of analysis*

EN 71-12:2016, *Safety of toys - Part 12: N-Nitrosamines and N-nitrosatable substances*

CEN/TR 16792:2014, *Safety of children's clothing - Recommendations for the design and manufacture of children's clothing - Mechanical safety*

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:

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

3.1

soother holder

article that consists of a soother fastener, a garment fastener and a connecting device in between, e.g. a strap

3.2**soother**

article which includes a teat and which is intended to satisfy the non-nutritive sucking need of children

Note 1 to entry: Soothers are also known as pacifiers or babies' dummies.

3.3**garment fastener**

device to attach and detach to any other product

Note 1 to entry: Any other product could be a stroller, car seat, plush product, etc.

3.4**soother fastener**

device for attaching the soother holder to the soother

3.5 Connecting devices**3.5.1****cord**

piece of slender, flexible material including monofilaments, woven and twisted cord, rope, and fibrous materials commonly called string, normally having a circular cross section

Note 1 to entry: See B.5.

3.5.2**strap**

connecting device made of flexible material with a non-circular cross section

3.5.3**chain**

connecting device made of multiple interlinked parts

3.6**touch-and-close device**

device having interlocking faces, which are secured when pressed together

3.7**press stud**

device with two parts that engage when pressed together

3.8**ventilation hole**

hole of any shape that includes a circular area of at least 4 mm diameter

Note 1 to entry: See B.7.

3.9**supplementary component**

part that is attached to the soother holder other than fasteners, press studs or touch-and-close devices and soothers and the part connecting the two fasteners

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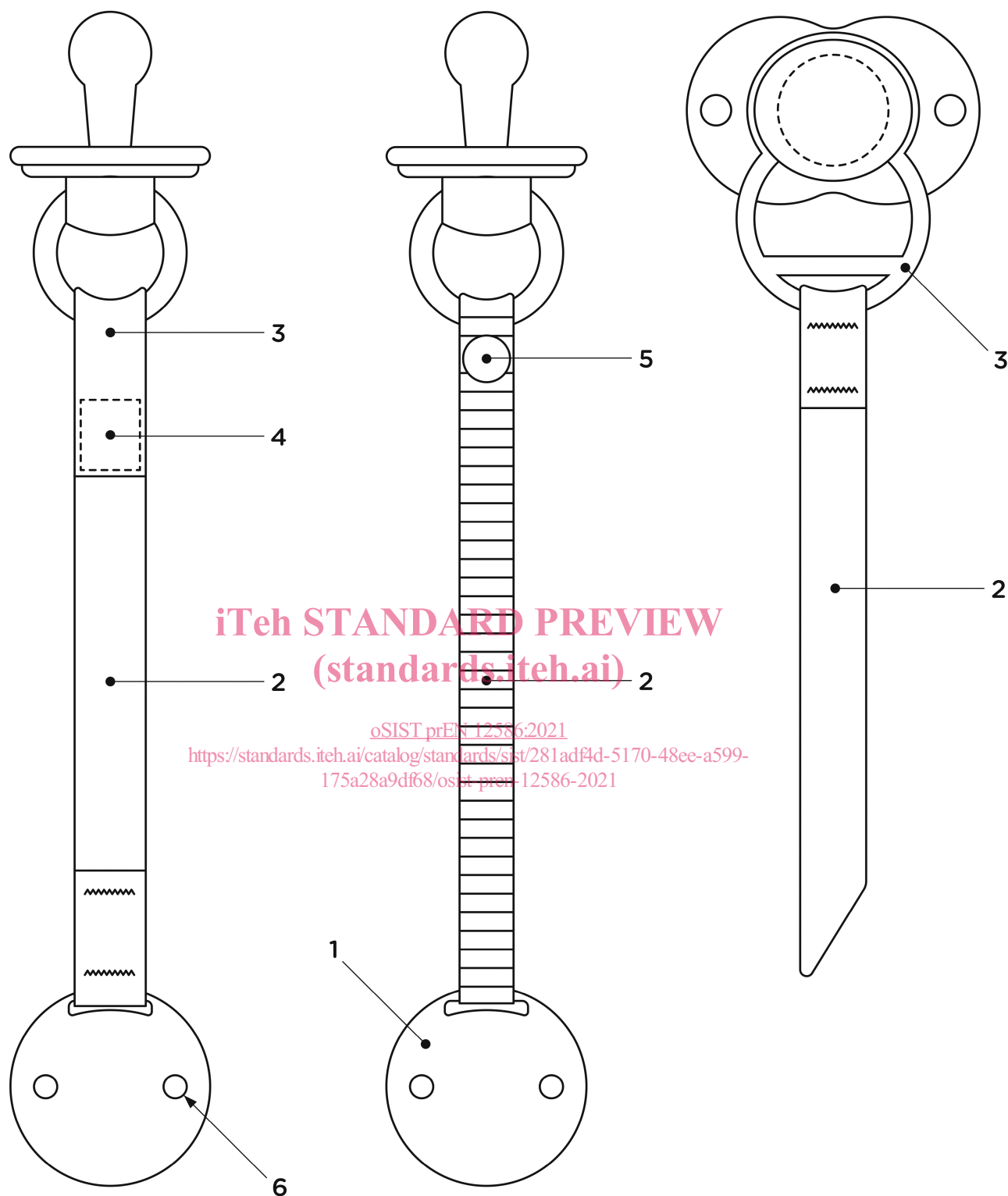
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4 Description of a soother holder

Figures 1 to 3 illustrate typical examples of different items of soother holders and their design features.

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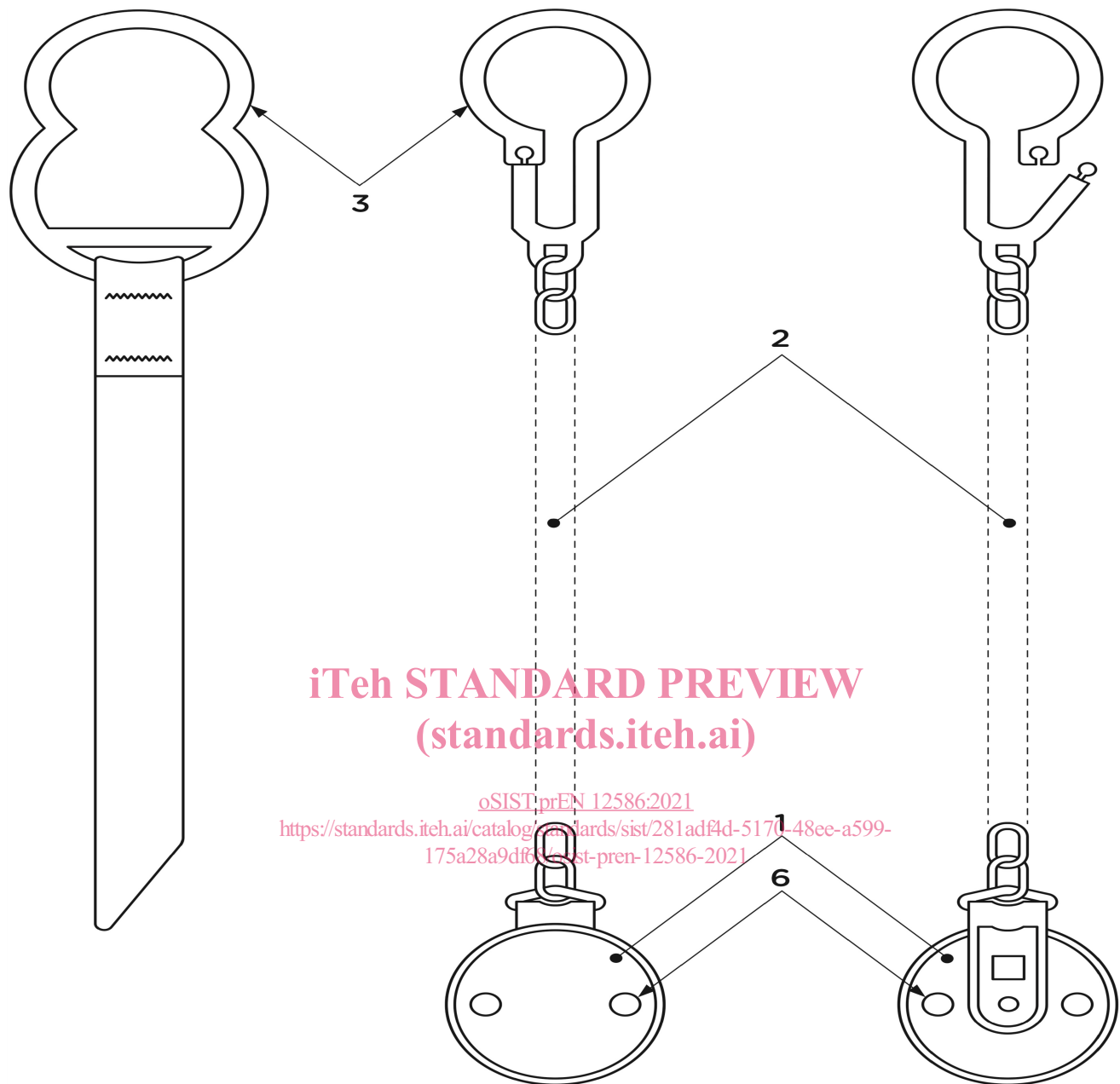
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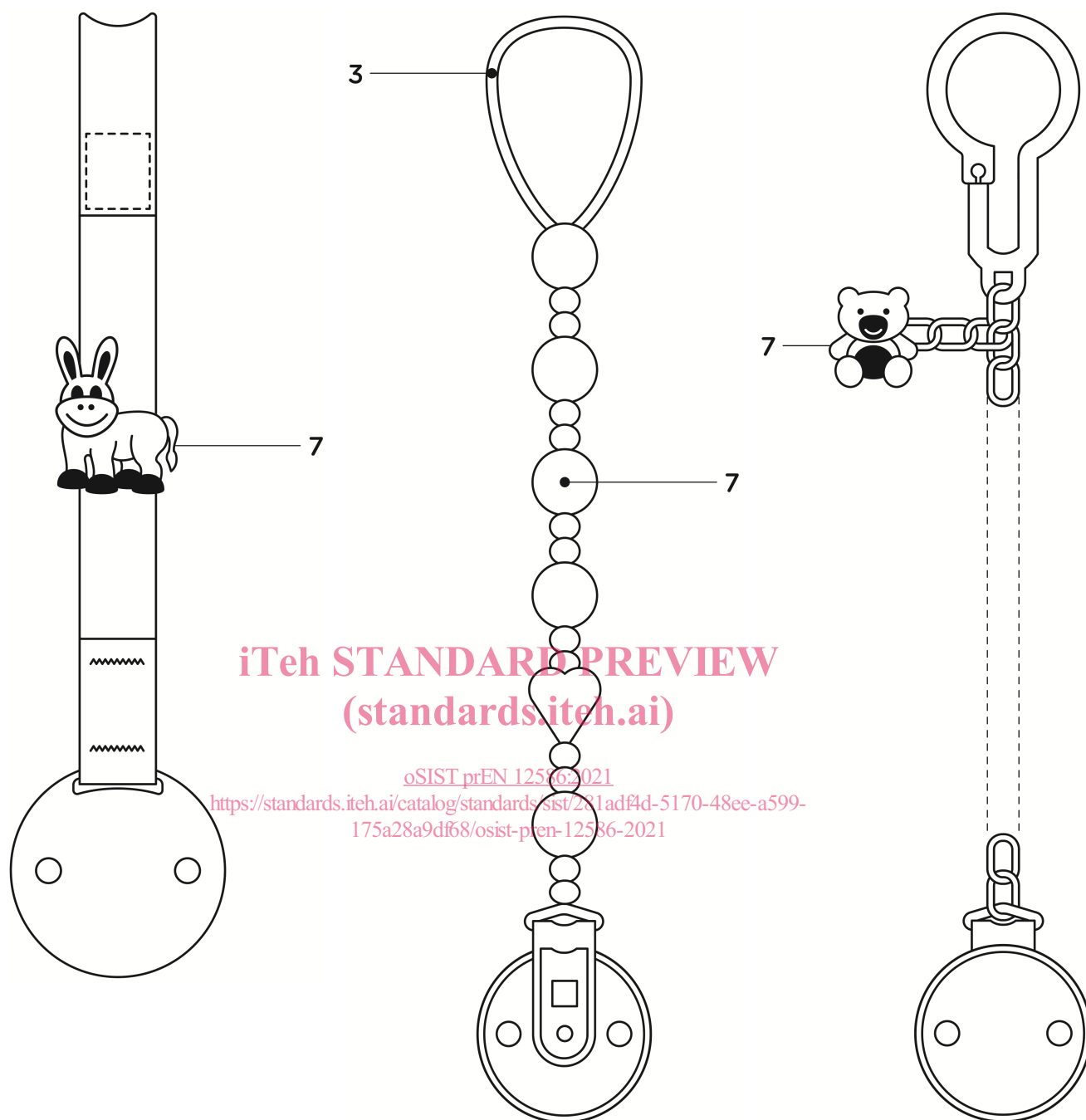
- | | |
|---------------------|--------------------------|
| 1 garment fastener | 4 touch and close device |
| 2 connecting device | 5 press stud |
| 3 soother fastener | 6 ventilation hole |

Figure 1 — Examples of soother holders or parts of soother holders assembled with soothers

**Key**

- 1 garment fastener
- 2 connecting device
- 3 soother fastener
- 4 ventilation hole

Figure 2 — Examples of soother holders or parts of soother holders

**Key**

- 1 soother fastener
- 2 supplementary component

Figure 3 — Examples of soother holders or parts of soother holders with supplementary components

5 Test equipment and tolerances

5.1 Guides

Dimensions in millimetres

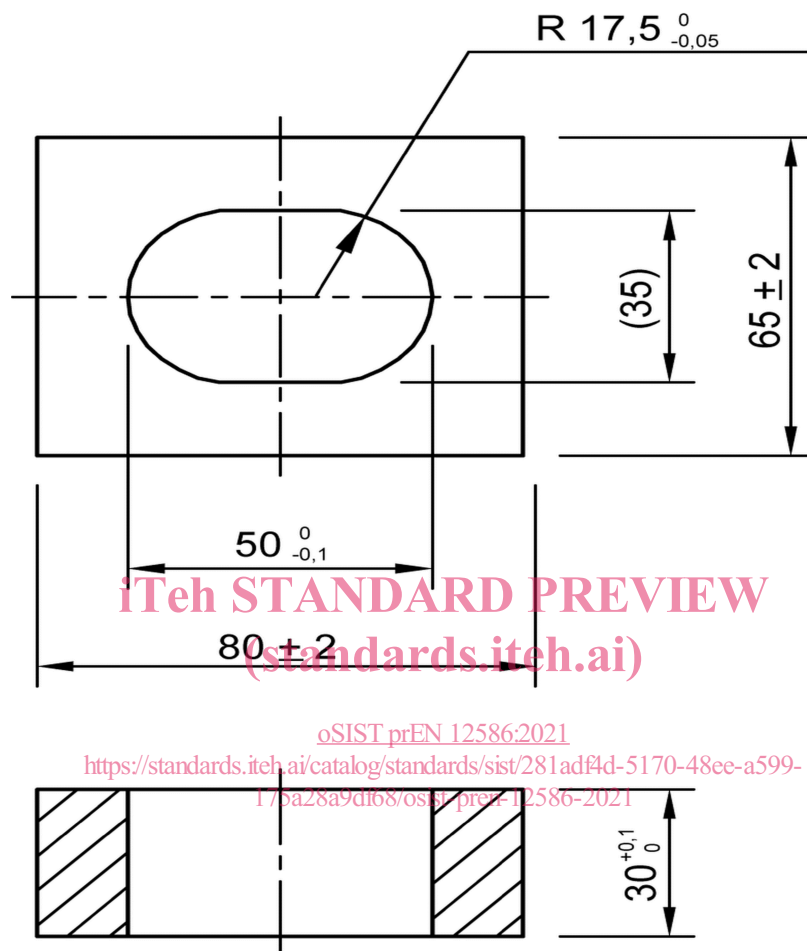


Figure 4 — Guide 1

Dimensions in millimetres

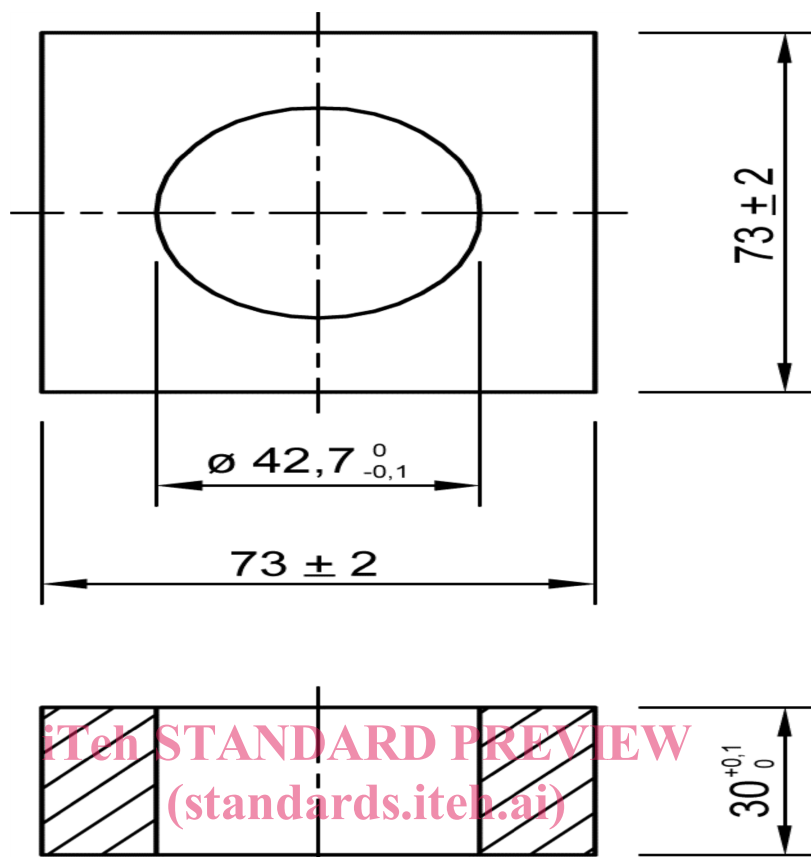


Figure 5 — Guide 2