Content

Title：	Operation Directions Governing the Inspection of Soother holder Ch
Date：	2026.08.12
Legislative：	1.Adopted and promulgated by the Bureau of Standards, Metrology and Inspection, Ministry of Economic Affairs, on 12 August 2026.
Content：	1. These Directions are established by the Bureau of Standards, Metrology and Inspection (BSMI) for the purpose of implementing the inspection of soother holder that are subject to mandatory inspection. 2. Inspection Scope: soother holders. 3. Inspection Schemes: Type-Approved Batch Inspection or Registration of Product Certification (Module II Type Test + Module III Declaration of Conformity to Type) at the choice of the applicant. 4. Inspection Standard: CNS 16041 “Child use and care articles - Soother holder.” 5. Inspection Items (1) Quality items: inspected in accordance with CNS 16041 as follows: a. General requirements: inspected in accordance with CNS 16041 Section 5.1. b. Mechanical Requirements: inspected in accordance with CNS 16041 Section 5.2. c. Chemical Requirements: inspected in accordance with CNS 16041 Section 5.3.3, 5.3.6.1, 5.3.7, and 5.3.10 for "Migration of Certain Elements", "Formaldehyde", "Phthalates/ Phthalate esters", and "Monomers" respectively. d. Toys: inspected in accordance with Attachment 2 to the Operation Directions Governing the Inspection of Toys. (2) Chinese labeling: The following items shall be checked in accordance with the Commodity Labeling Act and CNS 16041: a. Matters required to be labeled: checked in accordance with Article 6 of the Commodity Labeling Act and Section 7 and 8 of CNS 16041. For products incorporating toy components, the labeling requirement under Section 8.3 (f) do not apply. b. Labeling method: the required labeling shall be affixed to the body of the commodity, inner or outer packaging, or the user instructions. (3) Commodity Inspection Mark: the obligatory inspection applicant shall self-print the Commodity Inspection Mark in accordance with the Regulations Governing the Use of Commodity Inspection Marks and affix it to the body of the commodity or its smallest unit packaging. 6. Relevant Requirements for Type Testing (1) Principles for type determination a. Same type: Soother holder with the same country of manufacture. b. Main type: among commodities of the same type, the soother holder product of the same model with the maximum length and the minimum number of ventilation holes. c. Series type: soother holder of the number of ventilation holes other than the main type.

(2) Acceptance body for type testing: applications for type testing shall be accepted by BSMI-designated testing laboratories.
(3) Type-testing items: except for toy parts attached to the commodity, which shall be tested in accordance with Clause 5.(1).d, the remaining test items are as follows:
a. Main type: under Clause 5.(1).a, as well as Clause 5.(1).b and Clause 5.(2).
b. Series type: "holes" under Clause 5.(1).a; and "impact resistance" under Clause 5.(1).b; and Clause 5.(2).
(4) Type testing principles: One product item shall be inspected for the main type and for each series type. Where a series type includes multiple models, the length of each model shall first be measured in accordance with CNS 16041 Clause 6.1.3; the model with the maximum length shall then be selected and inspected in accordance with Clause 6.(3).b. Additional inspection items may be added if necessary.
(5) When applying for type testing, the applicant shall submit the following electronic documents and samples to the acceptance body for type testing:
a. Commodity type classification form (Attachment 1).
b. Color photos of the soother holder (4x6 inch or larger-sized photos showing the front, rear and side views of the product).
c. Samples of the Chinese labels.
d. Product information, including a product structure diagram and parts list (with the specifications, materials and photos of each component).
e. Declaration of Materials Validation for Domestic Use (Attachment 2)
f. Samples: Two soother holder sample of the main type and two soother holder sample of each series type shall be submitted. The acceptance body for type testing may require additional test samples if necessary.
(6) Type-testing fees: The fees shall be collected in accordance with the fee schedule specified by the BSMI-designated testing laboratories.

7. Relevant Requirements for Type-Approved Batch Inspection:
(1) The obligatory inspection applicant shall first obtain a type approval certificate. Beginning July 1, 2027, before the commodity is released from the factory premises or imported, the obligatory inspection applicant shall submit an inspection application to the BSMI or any of its branches (hereinafter referred to as the "inspection authority"). At the time of application, the date of manufacture shall be entered as required, and the Commodity Inspection Mark shall be self-printed and affixed to the body or its smallest unit packaging of the commodity. The commodity may be released from the factory premises or imported only after passing inspection.
(2) When applying for a type approval certificate, the obligatory inspection applicant shall prepare the type-test report and the documents specified in Clause 6.(5), and submit them, together with the documents specified in Subparagraph 1, Paragraph 1, Article 5 of the Regulations Governing Type Approval of Commodities, to the inspection authority for issuance of the certificate.
(3) Review period of type approval: 14 working days from the date on which the inspection authority receives the application, excluding the time for submission of supplementary information. Where additional samples are drawn, the review period shall be extended by another 7 working days
from the date on which the samples are received.
(4) Commodity Inspection Mark:
a. The self-printed Commodity Inspection Mark is comprised of a graphic symbol and an identification number, which consists of a Roman letter "T" and a designated code. The designated code includes a QR code. The identification number shall be placed to the right or below the graphic

symbol.
Example:

Note:
T00000 represents the identification number under the Type-Approved Batch Inspection procedure. It consists of the Roman letter "T" and the designated code shown on the type approval certificate. Different designated codes are assigned to different firms.
b. The designated code referred to in Clause 7.(4).a shall be issued by the inspection authority when the obligatory inspection applicant applies for type approval certificate.
c. The QR code referred to in Clause 7.(4).a shall be automatically generated by the system after the obligatory inspection applicant enters the identification number and selects the product category in the BSMI Inspection Mark QR Code Application System.
(5) Soother holder covered by the same application shall be of the same type and filed by the same obligatory inspection applicant.
(6) After confirming that the soother holder covered by the inspection application have been registered under the type approval certificate, the inspection authority shall randomly sample batches for inspection at a probability of 20% for commodities covered by the same inspection application. For each selected batch, one item shall be randomly selected from every three items listed in the same inspection application. Where fewer than three items are listed, they shall be counted as three items; at least one item and no more than five items shall be selected. One sample shall be randomly taken from each selected item for inspection, and its Chinese labeling and Commodity Inspection Mark shall be checked. When necessary, the inspection authority may increase the number of items selected for inspection and the number of samples taken.
(7) For batches not sampled, the inspection authority accepting the inspection application shall conduct a documentary review.
(8) For samples taken for inspection, the inspection unit commissioned by the BSMI to perform the inspection shall select two of the following four construction test items specified "holes" under Clause 5.(1).a; and "impact resistance" under Clause 5.(1).b."
(9) Inspection period: 5 working days from the day following the date on which the samples are delivered to the inspection unit referred to in the preceding subparagraph.
(10) Where prior release of the products is approved by the inspection authority, the obligatory inspection applicant shall, after the products are transported to the storage site, notify the inspection authority to take samples, seal the products or check the Commodity Inspection Mark and Chinese labeling.
(11) Nonconforming cases shall be handled in accordance with the Regulations Governing the Disposition of Commodities Failing Inspection by return shipment, destruction, or submission of an improvement plan. Items that pass inspection may be released separately, subject to the following requirements:
a. For nonconforming commodities to be returned or destroyed in whole batches, the Procedures for Commodity Return Shipment and Destruction shall apply.
b. Where the obligatory inspection applicant intends to make improvements to nonconforming commodities so that they comply with the inspection requirements and then apply for re-inspection, the obligatory inspection applicant shall apply to the BSMI for re-inspection by submitting the nonconformity notice, import declaration (not required for domestically manufactured products), validation declaration showing that the items not selected comply with the test items specified in Clause 7.(8) (not required if there are no non-selected items), an improvement plan, and a new inspection application, and shall also attach validation proof for any replaced parts. After approval is granted by the BSMI, the obligatory inspection applicant shall prepare the re-inspection approval

letter/reply form, nonconformity notice, and supervised improvement/destruction record, and file them directly to the original inspection authority for re-inspection
c. Where a new application was made, the sampling rate of items specified in Clause 7.(6) applies. The previously non-compliant items after corrective actions are taken shall be subject to inspection and the number of samples drawn for testing is doubled.
(12) If a sampled batch fails to comply with the inspection requirements, the soother holder filed by the same obligatory inspection applicant shall pass inspection for three consecutive batches before the simplified random batch inspection method under Clause 7.(6) may apply.
(13) If there are any changes to the scope of the products listed in the type approval certificate, such as changes to the main type or series type, the applicant shall obtain a new type-test report from the testing laboratory that issued the original report and apply to the inspection authority for a replacement certificate.

8. Relevant Requirements for Registration of Product Certification (RPC):
(1) For commodities subject to Registration of Product Certification, beginning July 1, 2027, before a commodity is released from the factory premises or imported, the obligatory inspection applicant shall obtain an RPC certificate, self-print the Commodity Inspection Mark, and affix it to the body of the commodity. The commodity may be released from the factory premises or imported only after these requirements are fulfilled.
(2) When applying for an RPC certificate, the applicant shall first obtain a type-test report in accordance with Clause 6, and then submit the documents specified in Subparagraph 1, Paragraph 1,
Article 4 of the Regulations Governing Registration of Product Certification, the conformity assessment documents (namely declaration of conformity to type), and the documents specified in Clause 6.(5) to the inspection authority for issuance of the certificate.
(3) Review period of RPC: 14 working days from the date on which the inspection authority receives the application, excluding the time required for submission of supplementary information. Where additional samples are drawn, the review period shall be extended by another 7 working days
from the date on which the samples are received.
(4) Commodity Inspection Mark:
a. The self-printed Commodity Inspection Mark is comprised of a graphic symbol and an identification number, which consists of a Roman letter “R” and a designated code. The designated code includes a QR code. The identification number shall be placed to the right or below the graphic symbol.
Example:

Note:
R00000 represents the identification number under the RPC. It consists of the Roman letter “R” and the designated code shown on the RPC certificate. Different numbers are assigned to different firms.
b. The designated code referred to in Clause 8.(4).a shall be issued by the inspection authority when the obligatory inspection applicant applies for the RPC certificate.
c. The QR code referred to in Clause 8.(4).a shall be automatically generated by the system after the obligatory inspection applicant enters the identification number and selects the product category in the BSMI Inspection Mark QR Code Application System.
(5) If there are any changes to the scope of the products listed in the RPC certificate, such as changes to main type or series type, the applicant shall obtain a new type-test report from the testing laboratory that issued the original report and apply to the inspection authority for a replacement

	certificate.
Attachments：	Attachment 1 Commodity Type Classification Form [Applicable to Soother Holder].pdf Attachment 2 Declaration of Materials Validation for Soother Holder.pdf Article 7.pdf Article 8.pdf

Data Source：Ministry of Economic Affairs R.O.C.(Taiwan) Laws and Regulations Retrieving System