

Legal Inspection Requirements for Soother Holders

By the Bureau of Standards, Metrology and Inspection (BSMI), Ministry of Economic Affairs

Background:

BSMI's market surveillance has shown that 67% of randomly purchased units failed the physical performance tests. In response to public concerns over the safety risks posed by soother holders, including the potential for choking and strangulation that may endanger infants and children, the Bureau of Standards, Metrology and Inspection (BSMI) includes these products within the scope of mandatory inspection to ensure their safety and quality.

Date of implementation: 1 July 2027

Products (HS/CCCN codes) covered:

Description of Goods	Inspection standard (note)	Reference C.C.C. Code (the first 6 digits are the same as HS Code)
Soother Holders	CNS 16041:2018	3926.90.90.90.8-E
Note: The listed products are exempt from testing under Sections 5.3.1, 5.3.2, 5.3.4, 5.3.5, 5.3.6.2, 5.3.8, 5.3.9, and 5.3.11.		

Inspection standards:

CNS 16041 Safety requirements for soother holders

Inspection items:

According to the characteristic properties of soother holders, tests for the chemical material and physical performance are included.

Conformity assessment procedures:

Type-Approved Batch Inspection (TABI) or Registration of Product Certification (RPC) Scheme [type test (Module II) + declaration of conformity to type (Module III)].

- Type-Approved Batch Inspection (TABI) Scheme

Further information on this scheme is available on the BSMI website at

<https://www.bsmi.gov.tw/wSite/ct?xItem=102867&ctNode=9846&mp=2>

- Registration of Product Certification (RPC) Scheme

Under this scheme, manufacturers or importers must have their products type-tested by the BSMI or BSMI-designated testing laboratories [type test (Module II)] before applying for registration of their products. Manufacturers or importers are also required to ensure, by declaration [declaration of conformity to type (Module III)], that all products made at their manufacturing facilities are in conformity with the prototypes submitted for type testing in Module II.

Products will be allowed to use the Commodity Inspection Mark with the letter "R" and the identification number given by the BSMI, after they are certified and registered with the BSMI. These products can then clear customs directly without any further inspection. The application fee and the annual fee for RPC are NT\$5,000 and NT\$2,000, respectively, for each type of

product, and a RPC certificate is valid for three years.

Further information on this scheme is also available on the BSMI website at

<https://www.bsmi.gov.tw/wSite/ct?xItem=102868&ctNode=9846&mp=2>

Related requirements:

1. The listed products shall be subject to mandatory inspection for both imported and domestically manufactured products starting from 1 July 2027. The import regulation code for the listed products is C02. The conformity assessment procedures shall adopt a dual-track system: either Registration of Product Certification [type test (Module II) + declaration of conformity to type (Module III)] or Type-Approved Batch Inspection. Starting from the date of this announcement, the BSMI will accept applications for Registration of Product Certification or Type Approval for the listed products. For products adopting Type-Approved Batch Inspection, a Type Approval certificate must first be obtained, and inspection shall be applied for prior to importation or prior to release from the factory for domestically manufactured products. For products adopting Registration of Product Certification, the conformity assessment procedures shall be conducted in accordance with the relevant provisions of the “Regulations Governing Registration of Product Certification.”
2. Certificates for the listed products will have a validity period of three years from the date of issuance (for certificates issued before 30 June 2027, the validity period will be three years starting from 1 July 2027).
3. Locations to apply for Type Testing: The BSMI-designated testing laboratories.
4. Locations to apply for Type Approval or Registration of Product Certification: The BSMI or its branches.
5. Locations to apply for Batch Inspection:
 - (1) Domestic manufacturers or commissioned manufacturers shall submit inspection applications to the BSMI or its branches according to the location of the production premises. Cross-jurisdictional inspections may be requested if necessary.
 - (2) Importers or commissioned importers shall apply to the BSMI or its branches for inspection according to the jurisdiction of the port of entry. Cross-jurisdictional inspections may be requested if necessary.
6. The processing time for Registration of Product Certification or Type Approval is 14 working days, excluding the time for submitting supplementary documents or samples. An additional 7 working days will be added if random sample testing is required upon receipt of the samples.
7. Fees for product type-testing: Charged in accordance with the fee schedule of testing laboratories.
8. The inspection fees for the listed products shall be charged in accordance with the relevant provisions of the "Regulations Governing Fees for Commodity Inspection."
9. From 1 July 2027, the designated code of the Commodity Inspection Identification Number for the listed products shall include a QR code. The applicant shall, in accordance with the “Regulations Governing the Use of Commodity Inspection Mark,” print the code themselves and mark it in a prominent place on the product or the smallest package. For RPC certificates obtained before 30 June 2026, the commodity inspection mark may also be applied.

10. The technical documents, samples, type determination principles, test items, and simplified inspection procedures for Type-Approved Batch Inspection of the listed products shall be conducted in accordance with the "Operation Directions Inspection Governing the of Soother Holders."
11. The inspection standards for the listed products shall follow the version specified in this announcement. If an updated version becomes available, the BSMI shall announce its implementation date in a separate notice.
12. Listed products with combined or multifunctional features that fall within the mandatory inspection scope shall comply with the relevant inspection standards. Any included accessories falling within the mandatory inspection scope must also meet the applicable inspection requirements.
13. The C.C.C. Codes for the listed products are for reference only. The commodity must still comply with all applicable requirements before entering the market, even if its C.C.C. Code is assigned differently by the Customs Administration, Ministry of Finance, or the International Trade Administration, Ministry of Economic Affairs.