	Technical Specification for Verification and Inspection of Thermometers	S/N	CNMV 7
		Rev.	5

1. This Technical Specification is developed pursuant to Paragraph 2, Articles 14 and 16 of the Weights and Measures Act.

2. The date of promulgation, document number, date of enforcement and content of amendment are listed as follows:

Rev.	Date of Promulgation	Document No. (Ching-Piao-Szu-Tsu)	Date of Enforcement	Content of Amendment
1	02.06.2003	No.09240005170	01.07.2003	
2	11.14.2005	No.09440004100	01.01.2007	Extend the scope to electrical thermometers and set the requirements of verification and inspection for electrical thermometers.
3	12.26.2007	No.09640006550	01.01.2008	Indentify the scope and set the measuring range and temperatures for verification of basal thermometers.
4	10.19.2016	No.10540018500	10.19.2016	Ruled out mercury in glass type thermometers from verification due to they are not allowed to be used.
5	5.25.2022	No.11140003550	5.25.2022	In coordination with the amendment of Regulations Governing Verification and Inspection of Measuring Instruments, add relevant regulations for the sampling verification of thermometers.

Date of Promulgation **5.25.2022**	**Bureau of Standards, Metrology and Inspection, Ministry of Economic Affairs**	Date of Enforcement **5.25.2022**

NO GUARANTEE ON THE TRANSLATION
In case of discrepancies between the English translation and Chinese text, the Chinese text shall govern.

1. Scope: this specification applies to electrical thermometers for human use (hereinafter referred to as "thermometers") and subject to verification and inspection. The thermometers use for measuring skin temperature is excluded from this specification.

2. Definition: A maximum device is the component of a thermometer that monitors over a specified time the temperature measured by a probe in contact with a body cavity or tissue, after which it indicates the maximum temperature and maintains the indication until reset by the user.

3. Structure

3.1 A thermometer shall bear the manufacturer's trade name or trademark.

3.2 The unit of temperature is the degree Celsius, symbol ˚C.

3.3 The minimum scale interval of a thermometer shall not be more than 0.1 ˚C.

3.4 The measuring range shall be a minimum of 35.5 ℃ to 42.0 ℃, and the range 35.5 ℃ to 42.0 ℃ shall be continuous. However, the basal thermometer's measuring range can be from 35.5 ℃ to 38.0 ℃.

3.5 The digital display of temperature of a electrical thermometers shall be complete without broken or incomplete.

4. Verification, inspection and maximum permissible errors

4.1 Verification and inspection equipment:

(1)Reference thermometer: the measuring range of the reference shall be a minimum of 35.5 °C to 42.0 °C with an expanded uncertainty no greater than 0.03 ℃ (calculated for a coverage factor k = 2). The calibration shall be traceable to national measurement standards.

(2)Reference water bath: a well-regulated and stirred water bath containing at least one litre in volume shall be used to establish reference temperatures over the measuring range for conducting various performance tests on an instrument. The bath shall be controlled to a temperature stability of better than ± 0.02 ℃ over the specified temperature range and shall not have a tempereature. This temperature gradient shall be assured under all conditions and methods of loading temperature probes.

4.2 Verification and inspection of errors of a thermometer shall be carried out at three temperatures: 35.5 ˚C, 37 ˚C and 41 ˚C. However, a basal thermometer can be carried out at two temperatures: 35.5 ˚C and 37 ˚C only.

4.3 The maximum permissible errors of verification of thermometers shall be ± 0.1 ℃.

4.4 The maximum permissible errors of in-service inspection shall be as small as the maximum permissible errors of verification.

4.5 Thermometers may be verified by sampling, the sampling verification of thermometers referred to in the preceding paragraph shall be continuous sampling. After the thermometers of same model number pass the verification for successive 1000 pieces of different batches, the sampling verification may be conducted with one-tenth of total quantity applied for verification starting from the next batch. If all sampled pieces pass the verification, all

thermometers of the application shall be deemed to comply. The piece-by-piece verification shall be resumed immediately if any piece fails to meet the requirements of measurement error while performing sampling verification. The batch followed shall not resume sampling verification until there are 1000 successive pieces passing verification.

4.6 Before the implementation of sampling verification, the applicant shall provide the permit license of medical devices issued by the Ministry of Health and Welfare, and the quality control record for thermometers of the given batch.

5. The verification compliance marks: the mark shall be attached to a prominent place of the body of the thermometer.