COMMISSION DIRECTIVE

of 18 July 1984

adapting to technical progress Directive 76/764/EEC on the approximation of the laws of the Member States relating to clinical mercury-in-glass maximum-reading thermometers

(84/414/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 71/316/EEC of 26 July 1971 on the approximation of the laws of the Member States relating to common provisions for both measuring instruments and methods of metrological control (1), as last amended by Directive 83/575/EEC (2), and in particular Article 17 thereof,

Whereas, since the adoption of Directive 76/764/EEC on the approximation of the laws of the Member States on clinical mercury-in-glass maximum-reading thermometers (3), as amended by Directive 83/128/EEC (4), new techniques have been developed in this field; whereas these techniques have made it necessary to conduct additional tests in order to establish the quality of the glass employed; whereas the Annexes to that Directive must, therefore, now be amended and modified in several points; whereas in the interests of clarity it is therefore appropriate to adopt a consolidated text for those Annexes;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Committee for the Adaptation to Technical Progress of Directives on the Removal of Technical Barriers to Trade in Measuring Instruments,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes I and II to Directive 76/764/EEC are hereby replaced by the Annexes to this Directive.

Article 2

Member States shall bring into force laws, regulations and administrative provisions necessary to comply with this Directive on 1 January 1986. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 18 July 1984.

For the Commission

Karl-Heinz NARJES

Member of the Commission

(1) OJ No L 202, 6. 9. 1971, p. 1.
(2) OJ No L 332, 28. 11. 1983, p. 43.
(3) OJ No L 262, 27. 9. 1976, p. 139.
(4) OJ No L 91, 9. 4. 1983, p. 29.

ANNEX I

1. UNIT OF TEMPERATURE

The unit of temperature employed for thermometer graduation shall be the degree Celsius.

2. SCALE RANGE AND GRADUATION

The thermometers shall have a scale range of at least 35,5 to 42,0 °C, the value of the scale divisions being 0,1 of a degree Celsius.

3. TYPES

3.1. Thermometers may be of the solid-stem or enclosed-scale type.

3.1.1. In the case of solid-stem thermometers, the scale shall be marked on the solid-stem.

3.1.2. In the case of enclosed-scale thermometers, the scale shall be marked on a scale panel fixed logitudinally behind the capillary tube; the capillary tube and the scale panel shall be enclosed in a transparent tube impermeably fixed to the bulb and forming a protective sheath.

3.2. Thermometers shall be provided with a maximum-reading device which prevents the mercury column from retracting when the thermometer cools.

4. MATERIALS

4.1. Thermometer bulbs shall be made of a type of glass which satisfies the conditions set out in Annex II. This glass shall be clearly and indelibly identified by either:

4.1.1. an integral mark introduced by the glass manufacturer in such a way as to be clearly recognizable in the bulb after manufacture of the thermometer,

4.1.2. or a mark chosen by the glass manufacturer and affixed by the thermometer manufacturer and clearly indicating the type of glass employed. The conformity of this glass with that approved in accordance with item 11.1.1 shall be confirmed by a certificate of conformity issued by the glass manufacturer.

4.2. The glass used for the maximum-reading device and capillary tube shall have a hydrolytic strength as specified in item 1 of Annex II.

4.3. The scale panels of enclosed-scale thermometers shall be of opaline, metal or a material of equivalent dimensional stability.

4.4. The sheaths of enclosed-scale thermometers shall be of glass.

5. DESIGN

5.1. The thermometer shall be free of any fault which could prevent normal functioning or result in user error.

5.2. The ends of the thermometer shall be so formed as to preclude any risk of accident during use.

5.3. The capillary tube shall be such that the entire length of the mercury column and the meniscus are clearly visible from one angle. It shall be prismatic in form and have a magnifying effect, or be so designed as to ensure equal ease of reading.

5.4. The mercury shall be sufficiently pure and dry.
In order to ensure that the thermometer functions correctly, the bulb, capillary tube and mercury shall be free of gas, glass fragments and foreign bodies.

5.5. The mercury column shall rise uniformly, without appreciable surges, when the thermometer is heated slowly. It shall fall below the lowest numbered scale line when the mercury is subjected to an acceleration of 600 m/s^2 at the bottom of the bulb after the thermometer has been brought to a temperature of not less than 37 °C and then cooled to a temperature below the minimum scale value.

5.6. In enclosed-scale thermometers, the scale panel shall be in direct contact with the capillary tube and fixed sufficiently firmly in the sheath to prevent any displacement with respect to the tube. The panel shall be so positioned as to ensure that any displacement thereof with respect to the capillary tube can be easily detected by means of an indelible mark on the sheath, level with a numbered scale mark, or by some equivalent means.

5.7. The sheaths of enclosed-scale thermometers shall be free of moisture, mercury, glass fragments and foreign bodies.

6. GRADUATION AND NUMBERING

6.1. The scale divisions shall be clearly and uniformly marked. The scale lines and numbering shall be engraved or printed clearly and indelibly.

6.2. The length of the scale divisions shall be not less than 0,5 mm in the case of solid-stem thermometers and not less than 0,6 mm in that of enclosed-scale thermometers.

6.3. The scale lines shall be perpendicular to the axis of the thermometers and their thickness shall not exceed one-fifth of the length of a scale division plus 0,05 mm in enclosed-scale thermometers, or one-quarter of the length of a scale division plus 0,05 mm in solid-stem thermometers.

6.4. Scale lines representing whole degrees and half-degrees shall be longer than the other scale lines.

6.4. Scale lines representing whole degrees shall be numbered. Numbering of the line corresponding to 37 °C shall be optional in the case of solid-stem thermometers and may take the form specified in item 6.5.

6.5. The line representing the temperature of 37 °C may be rendered conspicuous by means of a colour different from that used for the numbering and/or by an additional mark.

6.6. Scale lines and figures shall be so located as to be visible at the same times as the mercury column.

7. MARKS

7.1. The stem of solid-stem thermometers and the scale panel of enclosed-scale thermometers shall bear the following indelible marks:

7.1.1. The unit-of-temperature symbol '°C'.

7.1.2. The EEC pattern-approval sign in accordance with item 3.5 of Annex I to Directive 71/316/EEC; by way of derogation from the general rule set out in item 3.1 of that Annex, the EEC pattern-approval sign may be composed of the undermentioned marks in the following order:

— the stylized letter 'ε',

— the letter or letters denoting the Member State which granted EEC pattern approval,

— the year of approval,

— a mark to be determined by the metrological service which granted EEC pattern approval, clearly separated from the year.

7.1.3. The manufacturer's trade mark or business name.

7.1.4. Where applicable, the mark provided for in item 4.1.2.

7.2. Other inscriptions may be added, provided that they are not likely to mislead the user or give rise to difficulty in reading the thermometer.

No indication of the measuring period shall appear on the instruments.

8. MAXIMUM PERMISSIBLE ERROR

The maximum permissible error is + 0,10 to — 0,15 of a degree Celsius. These limits apply to stabilized thermometer readings.

A stabilized reading is that given by a thermometer which after attaining thermal equilibrium with a water bath at a temperature within the thermometer scale range, has been cooled to a temperature of between 15 and 30 °C.

9. INFLUENCE OF IMMERSION TIME

If a thermometer at the temperature t_1 (15 °C $\leqslant t_1 \leqslant$ 30 °C) is suddenly immersed in a vigorously stirred water bath at a constant temperature t_2 (35,5 °C $\leqslant t_2 \leqslant$ 42 °C) and withdrawn after 20 seconds, the thermometer reading shall satisfy the following conditions after cooling to ambient temperature (15 to 30 °C):

1. it must lie within the limits of the maximum permissible error;

2. it must not differ by more than 0,005 ($t_2 - t_1$) from the stabilized reading for temperature t_2.

10. POSITION OF THE EEC INITIAL VERIFICATION MARK

10.1. A space for the EEC initial verification mark shall be reserved on the stem of solid-stem thermometers and on the sheath of enclosed-scale thermometers.

10.2. In accordance with item 3.1.1 of Annex II to Directive 71/316/EEC and notwithstanding the general rule specified in item 3 of that Annex, the verification mark may consist of the undermentioned marks in the following order:

— the small letter 'e',

— the letter or letters denoting the Member State in which initial verification took place,

— the year of initial verification,

— where necessary, the distinguishing number of the verifying office, separated clearly from the year.

10.3. In the case of sandblasted marks, the letters and figures shall be broken at appropriate points in such a way as to avoid impairing their legibility.

11. EEC PATTERN APPROVAL AND INITIAL VERIFICATION

11.1. **EEC pattern approval**

11.1.1. At the time of EEC pattern approval, thermometers shall be examined for the purpose of checking their conformity with the technical and metrological requirements set out in this Annex. In addition, the tests in Annex II shall be performed.

11.1.2. All manufacturers of thermometers using for the manufacture of the bulb a glass not marked by the glass manufacturer shall communicate to the competent department the mark referred to in item 4.1.2 and the chemical composition of the glass as guaranteed by the glass manufacturer.

11.2. **EEC initial verification**

The EEC initial verification examination shall be conducted in order to establish the conformity of thermometers with the approved pattern.

11.2.1. In order to check that thermometers satisfy the requirements set out in items 8 and 9 of this Annex, the following test shall be performed:

The thermometers shall be checked in vigorously stirred water baths against standard thermometers. This check shall be performed at at least two temperatures differing by at least four degrees Celsius between 35,5 and 42,0 °C.

During this check, the thermometers shall be immersed for 20 seconds at one temperature and 40 seconds at the other, the temperatures or immersion periods being alternated at regular intervals.

The thermometers shall be kept in the vertical position and, in each instance, readings shall be taken after removal from the bath and after return to ambient temperature.

The accuracy with which the error is determined shall be equal to or better than 0,03 of a degree Celsius. This examination shall be carried out not less than 15 days after reception of the thermometers.

11.2.2. Where thermometer bulbs are manufactured from a glass which has not been identified by the glass manufacturer, the following conditions shall be met:

(a) the certificate mentioned in item 4.1.2. relating to thermometers presented for EEC initial verification shall be kept at the disposal of the competent department;

(b) an analysis to determine the chemical composition of the glass used in the bulbs of thermometers presented for EEC initial verification shall be carried out periodically, on the initiative of the competent department, in order to check its conformity with the approved glass.

ANNEX II

CONDITIONS TO BE SATISFIED BY THE GLASS USED IN THE MANUFACTURE OF THE BULBS

1. HYDROLYTIC STRENGTH

During the analysis of the glass in accordance with ISO Standard 719-1981 (determination of the hydrolytic strength of granulated glass at 98 °C), the quality of alkali dissolved for 1 g of glass shall not exceed 263,5 µg of Na_2O.

2. AVERAGE ZERO POINT DEPRESSION

Zero point depression shall be determined with special test thermometers without a maximum-reading device, made from the glass to be tested and in accordance with requirements laid down by the competent department.

2.1. The average zero point depression, as determined by the method described below, shall not exceed 0,05 of a degree Celsius.

2.2. The test thermometers shall satisfy the following conditions :

2.2.1. Minimum scale range : — 3,0 to + 3,0 °C.

2.2.2. Value of the scale divisions : 0,02, 0,05 or 0,1 of a degree Celsius.

2.2.3. The length of the scale division shall be not less than 0,7 mm in the case of enclosed-scale thermometers and not less than 1,0 mm in the case of solid-stem thermometers.

2.2.4. The expansion chamber shall be sufficiently large to allow the thermometer to be heated to a temperature of 400 °C without damage.

2.3. Each test thermometer shall be checked for correct stabilization in accordance with the following provisions :

2.3.1. The thermometer shall be heated in a temperature-controlled enclosure (liquid bath or furnace) from ambient temperature to 350 ± 10 °C and held at that temperature for not less than five minutes. It shall then be cooled to 50 °C in the temperature-controlled enclosure, the enclosure temperature decreasing at a rate of 10 to 15 degrees Celsius per hour.

2.3.2. When the thermometer has reached a temperature of 50 °C, it shall be removed from the temperature-controlled enclosure and the correction to 0 °C determined (value K_1).

2.3.3. The thermometer shall then be heated to 350 ± 10 °C for a second time in a temperature-controlled enclosure and kept at that temperature for 24 hours. It shall then be cooled to 50 °C as described in item 2.3.1.

2.3.4. When the thermometer has reached a temperature of 50 °C, it shall be removed from the temperature-controlled enclosure and the correction to 0 °C shall again be determined (value K_2).

2.3.5. The absolute value of the difference between K_2 and K_1 shall not exceed 0,15 of a degree Celsius. Thermometers which do not meet this requirement cannot be used for the determination of zero point depression.

2.4. **Test procedure**

2.4.1. Use shall be made of at least three thermometers which have satisfied the requirements of the stabilization test provided for in item 2.3 and which have not been heated above ambient temperature after the determination of K_2.

2.4.2. Each of these thermometers shall be checked at least three times in accordance with the provisions of items 2.4.2.1 to 2.4.2.3.

2.4.2.1. The thermometer shall be kept for a week at a temperature between 20 and 25 °C. At the end of the week the correction to 0 °C (value K_3) shall be determined.

2.4.2.2. The thermometer shall then be immersed in a test bath at a temperature of 100 ± 1 °C for 30 minutes, after which it shall be withdrawn and allowed to cool in air. Its bulb must not be in contact with other objects during cooling to ambient temperature.

2.4.2.3. The correction to 0 °C shall be determined within 15 minutes after the thermometer has been withdrawn from the test bath. The value of the correction obtained is designated K_4.

2.4.3. The procedures described in items 2.4.2.1 to 2.4.2.3 shall be repeated in order to obtain a series of *n* differences, $K_4 - K_3$, $K_6 - K_5$, . . ., $K_{2n+2} - K_{2n+1}$, which are the thermometer zero point depression values obtained during the first, second and nth series of measurements respectively.

2.4.4. When n series of measurements have been performed with m test thermometers, the average zero point depression of these thermometers is given by the expression :

$$\frac{1}{m \cdot n} \sum_{i=1}^{m} \left[(K_4{}^{(i)} - K_3{}^{(i)}) + (K_6{}^{(i)} - K_5{}^{(i)}) + \ldots + (K_{2n+2}{}^{(i)} - K_{2n+1}{}^{(i)}) \right]$$

In accordance with items 2.4.1 and 2.4.2, the conditions

$$m \geqslant 3 \text{ and } n \geqslant 3$$

must be fulfilled in respect of m and n.

The standard deviation of the average zero point depression determined in accordance with the preceding requirements shall not exceed 0,01 of a degree Celsius.