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.