# COUNCIL DIRECTIVE

## of 27 July 1976

## on the approximation of the laws of the Member States on clinical mercury-in-glass, maximum reading thermometers

(76/764/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

Whereas the mandatory provisions governing the manufacture and methods of control of clinical thermometers, differ from one Member State to another and hence hinder trade in those instruments; whereas these provisions accordingly require approximation;

Whereas 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 (3) has laid down the procedure for EEC pattern approval and EEC initial verification; whereas, in accordance with that Directive, technical requirements for manufacture and performance of clinical thermometers should be laid down,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

This Directive shall apply to clinical mercury-in-glass, maximum reading thermometers designed to measure the internal temperature of humans or animals.

*Article 2*

The clinical mercury-in-glass maximum reading thermometers eligible to bear the EEC mark shall be those described in the Annexes. They shall not be subject to EEC pattern approval; they shall be subject to EEC initial verfication.

*Article 3*

No Member State may prevent, prohibit or restrict the placing on the market or entry into use of clinical thermometers bearing the EEC initial verification mark.

*Article 4*

1. Member States shall put into force the laws, regulations and administrative provisions needed in order to comply with this Directive within four years of its notification and shall forthwith inform the Commission thereof.

2. Member States shall ensure that the text of the main provisions of national law which they adopt in the field covered by this Directive are communicated to the Commission.

*Article 5*

This Directive is addressed to the Member States.

Done at Brussels, 27 July 1976.

*For the Council*

*The President*

M. van der STOEL

(1) OJ No 63, 3. 4. 1967, p. 982/67.
(2) OJ No 30, 22. 2. 1967, p. 480/67.
(3) OJ No L 202, 6. 9. 1971, p. 1.

*ANNEX I*

1. TEMPERATURE UNIT

The temperature unit shall be the degree Celsius on the international scale employed for measurement of temperature.

2. SCALE RANGE

The scale range shall extend at least from 35·5 to 42 °C and the scale shall be divided into tenths of degrees Celsius.

3. TYPES

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

Thermometers of the solid-stem type shall have a prismatic stem on which the scale is indicated.

In thermometers of the enclosed-scale type the scale shall be indicated on a small, separate panel, both stem and panel being enclosed in a water-tight sheath.

Thermometers shall be fitted with a maximum reading device which prevents the mercury column from falling automatically when the mercury in the bulb returns to the surrounding temperature.

4. MATERIALS

The bulbs of thermometers shall be constructed of glass conforming to the requirements laid down in Annex II and identified visibly and indelibly:

— either by a mark affixed to the bulb by the producer of the glass,

— or by a mark affixed to any part of the thermometer, by its manufacturer, together with a certificate issued by the producer of the glass to the effect that it conforms to requirements.

The glass used for the maximum reading device and for the capillary space shall have adequate hydrolytic resistance (*).

The small panel showing the scale in the case of enclosed-scale thermometers shall be of silica, metal or any other material of an equivalent stability of design.

The thermometer stems shall be of capillary glass which gives an enlarged image of the mercury column. This should be legible at a glance throughout the whole of its length.

5. MANUFACTURER

The thermometer shall be free of any fault which could prevent its normal functioning or mislead the user.

The ends of the thermometer shall be formed in such a way as to avoid any risk of accident during its use.

The mercury shall be sufficiently pure and dry. The bulb, the capillary tube and the mercury shall be sufficiently free of gas to ensure that the thermometer functions correctly.

When, after it has been heated up to at least 37 °C, and has returned to the surrounding temperature, the thermometer is submitted to an acceleration of 600 m/s² at the base of the bulb, the mercury meniscus shall fall to below the lowest scale line.

In enclosed-scale thermometers, the panel showing the scale shall be placed in direct contact with the stem and shall be fixed in the sheath in such a way that it does not become detached from the stem.

(*) Glass may be regarded as having adequate hydrolytic resistance if, when analysed according to the provisions of ISO recommendation 719—1968 (calculation of the hydrolytic resistance of granulated glass at 98 °C), the quantity of alkali obtained in solution from 1 g of glass does not exceed 263·5 $\mu$g of $Na_2O$.