EUROPEAN COMMISSION
DG ENTERPRISE
Directorate G
Unit 4 - Pressure Equipment, Medical Devices, Metrology

MEDICAL DEVICES : Guidance document

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GUIDELINES RELATING TO THE APPLICATION OF :

THE COUNCIL DIRECTIVE 90/385/EEC ON ACTIVE IMPLANTABLE MEDICAL DEVICES

THE COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES

MEDICAL DEVICES WITH A MEASURING FUNCTION

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Background

Annex VII, paragraph 5 of MDD requires for class I devices with a measuring function that the manufacturer must also follow one of the procedures referred to in annex IV, V or VI, for the «aspects of manufacture concerned with the conformity of the products with the metrological requirements ».

It is therefore necessary to specify criteria for the existence of a « measuring function » in a medical device.

Criteria for devices with a measuring function

The following criteria, if fulfilled together, indicate that a device has a measuring function:

a) **<u>The device is intended by the manufacturer to measure</u>:**

- quantitatively a physiological or anatomical parameter, or
- a quantity or a qualifiable characteristic of energy or of substances delivered to or removed from the human body.

b) **<u>The result of the measurement</u>**

- is displayed in legal units or other acceptable units within the meaning of Directive 80/181/ECC[1] or
- is compared to at least one point of reference indicated in legal units or other acceptable units in compliance with the pre-mentioned directive.

c) The intended purpose implies accuracy, claimed explicitly or implicitly, where a non-compliance with the implied accuracy could result in a significant adverse effect on the patient's health and safety.

Note 1: The expression « claimed implicitly » covers cases where the user, on the basis of the designation of the device or of its accompanying documents, or on the basis of the common use is entitled to expect accuracy where the accuracy of the measurement has an impact on the diagnosis or therapy of the patient.

Note 2: Measuring activities during the manufacturing process including those for calibration purposes are not covered by this recommendation and do not imply a measuring function of the manufactured device.

Examples for devices with a measuring function

- device for measuring body temperature,

[1] OJ n° L39/40, 15.2.1980 as amended by Directive 89/617/EEC, OJ n° L357/28, 7.12.1989

- pacifier which includes a temperature display including those with only a change of colour where criteria b is met,
- device for indicating that a body temperature is above or below a specified value,
- non-active non-invasive device for measuring blood pressure ,
- non-active device for measuring intra-ocular pressure,
- device for measuring volume or pressure or flow of liquid or gases delivered to or removed from the human body (included any container with a graduation scale or with a single point graduation where criteria c is met).

Examples for devices without a measuring function

- patch for indicating trends of body temperature (where criteria b is not met),
- device for the delivery of liquid to the human body (e.g. medicine spoons, cups, droppers, without graduation or scale or display of measuring unit),
- device for displaying trends of physiological parameters (e.g. urine bags without graduation or scale, callipers for obesity),
- eye-test chart.