ANNEX I

ESSENTIAL REQUIREMENTS

B.DESIGN AND MANUFACTURING REQUIREMENTS

8. Information supplied by the manufacturer

8.1. Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.

This information comprises the data on the label and in the instructions for use.

As far as practicable and appropriate, the information needed to use the device safely and properly must be set out on the device itself and/or, where appropriate, on the sales packaging. If individual full labelling of each unit is not practicable, the information must be set out on the packaging and/or in the instructions for use supplied with one or more devices.

Instructions for use must accompany or be included in the packaging of one or more devices.

In duly justified and exceptional cases no such instructions for use are needed for a device if it can be used properly and safely without them.

[[X1]The decision whether to translate the instructions for use and the label into one or more languages of the European Union shall be left to the Member States, except that, for devices for self-testing, the instructions for use and the label must include a translation into the official language(s) of the Member State in which the device for self-testing reaches its final user.**]**

Editorial Information

X1 Inserted by Corrigendum to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (Official Journal of the European Communities L 331 of 7 December 1998).

8.2. Where appropriate, the information to be supplied should take the form of symbols. Any symbol and identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colour used must be described in the documentation supplied with the device.

8.3. In the case of devices containing or a preparation which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant danger symbols and labelling requirements of Directive 67/548/EEC[(1)] and Directive 88/379/EEC[(2)] shall apply. Where there is insufficient space to put all the information on the device itself or on its label, the relevant danger symbols shall be put on the label and the other information required by those Directives shall be given in the instructions for use.

The provisions of the aforementioned Directives on the safety data sheet shall apply, unless all relevant information as appropriate is already made available by the instructions for use.

8.4. The label must bear the following particulars which may take the form of symbols as appropriate:

(a) the name or trade name and address of the manufacturer. For devices imported into the Community with a view to their distribution in the Community, the label, the outer

packaging, or the instructions for use shall contain in addition the name and address of the authorised representative of the manufacturer;

(b) the details strictly necessary for the user to uniquely identify the device and the contents of the packaging;

(c) where appropriate, the word 'STERILE' or a statement indicating any special microbiological state or state of cleanliness;

(d) the batch code, preceded by the word 'LOT', or the serial number;

(e) if necessary, an indication of the date by which the device or part of it should be used, in safety, without degradation of performance, expressed as the year, the month and, where relevant, the day, in that order;

(f) in case of devices for performance evaluation, the words 'for performance evaluation only';

(g) where appropriate, a statement indicating the *in vitro* use of the device;

(h) any particular storage and/or handling conditions;

(i) where applicable, any particular operating instructions;

(j) appropriate warnings and/or precautions to take;

(k) if the device is intended for self-testing, that fact must be clearly stated.

8.5. If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state the intended purpose in the instructions for use and, if appropriate, on the label.

8.6. Wherever reasonable and practicable, the devices and separate components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.

8.7. Where appropriate, the instructions for use must contain the following particulars:

(a) the details referred to in section 8.4 with the exception of points (d) and (e);

(b) composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;

(c) the storage conditions and shelf life following the first opening of the primary container, together with the storage conditions and stability of working reagents;

(d) the performances referred to in section 3 of part A;

(e) an indication of any special equipment required including information necessary for the identification of that special equipment for proper use;

(f) the type of specimen to be used, any special conditions of collection, pre-treatment and, if necessary, storage conditions and instructions for the preparation of the patient;

(g) a detailed description of the procedure to be followed in using the device;

(h) the measurement procedure to be followed with the device including as appropriate:
— the principle of the method,

— the specific analytical performance characteristics (e.g. sensitivity, specificity, accuracy, repeatability, reproducibility, limits of detection and measurement range, including information needed for the control of known relevant interferences), limitations of the method and information about the use of available reference measurement procedures and materials by the user,

— the details of any further procedure or handling needed before the device can be used (for example, reconstitution, incubation, dilution, instrument checks, etc.),

— the indication whether any particular training is required;

(i) the mathematical approach upon which the calculation of the analytical result is made;

(j) measures to be taken in the event of changes in the analytical performance of the device;

(k) information appropriate to users on:

— internal quality control including specific validation procedures,

— the traceability of the calibration of the device;

(l) the reference intervals for the quantities being determined, including a description of the appropriate reference population;

(m) if the device must be used in combination with or installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe and proper combination;

(n) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely; information about safe waste disposal;

(o) details of any further treatment or handling needed before the device can be used (for example, sterilisation, final assembly, etc.);

(p) the necessary instructions in the event of damage to the protective packaging and details of appropriate methods of resterilisation or decontamination;

(q) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and resterilisation or decontamination, and any restriction on the number of reuses;

(r) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;

(s) precautions to be taken against any special, unusual risks related to the use or disposal of the device including special protective measures; where the device includes substances of human or animal origin, attention must be drawn to their potential infectious nature;

(t) specifications for devices for self-testing:

— the results need to be expressed and presented in a way that is readily understood by a lay person; information needs to be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result) and on the possibility of false positive or false negative result,

— specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device,

— the information provided must include a statement clearly directing that the user should not take any decision of medical relevance without first consulting his or her medical practitioner,

— the information must also specify that when the device for self-testing is used for the monitoring of an existing disease, the patient should only adapt the treatment if he has received the appropriate training to do so;

(u) date of issue or latest revision of the instructions for use.

(**1**) Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 196, 16.8.1967, p. 1). Directive as last amended by Commission Directive 97/69/EC (OJ L 343, 13.12.1997, p. 19).

(**2**) Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 187, 16.7.1988, p. 14). Directive as last amended by Commission Directive 96/65/EC (OJ L 265, 18.10.1996, p. 15).